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DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1773

RIN 0572–AC33

Policy on Audits of RUS Borrowers and Grantees

AGENCY: Rural Utilities Service, USDA.

ACTION: Final rule with request for comment.

SUMMARY: The Rural Utilities Service (RUS) is amending its regulations regarding its Policy on Audits to incorporate 2011 revisions to the Generally Accepted Government Auditing Standards (GAGAS) issued by the Government Accountability Office (GAO), the clarified audit standards issued by the American Institute of Certified Public Accountants (AICPA) in 2011, and Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, Subpart F, Audit Requirements, issued by the Office of Management and Budget on December 26, 2013, and adopted by USDA on December 26, 2014. RUS is also expanding and clarifying its regulations to: include grant recipients, amend its peer review requirements, amend its reporting requirements, expand the options for the electronic filing of audits, and clarify a number of existing audit requirements, and is amending the title to reflect this change.

DATES: *Effective Date:* Rule will become effective on July 6, 2018 and is applicable for financial audits for periods ending on or after December 15, 2018.

Comment Date: Comments must be received by RUS on or before June 6, 2018.

ADDRESSES: Submit comments by either of the following methods:

- Federal eRulemaking Portal at *https://www.regulations.gov/*. Follow instructions for submitting comments.
- *Postal Mail/Commercial Delivery:* Please send your comments addressed to Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, STOP 1522, Room 5164–S, Washington, DC 20250–1522.

Additional information about Rural Development and its programs is available on the internet at *https://www.rd.usda.gov/*.

FOR FURTHER INFORMATION CONTACT: William Chris Colberg, Acting Chief, Technical Accounting and Auditing Staff, Program Accounting Services Division, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, STOP 1523, Washington, DC 20250–1523. Telephone: (202) 720–1905.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12372

This final rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with state and local officials. See the final rule related notice entitled, ''Department Programs and Activities Excluded from Executive Order 12372'' (50 FR 47034) advising that RUS loans and loan guarantees were not covered by Executive Order 12372.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. RUS has determined that this final rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all state and local laws and regulations that are in conflict with this rule will be preempted, no retroactive effect will be given to this rule, and, in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)), administrative appeal procedures, if any, must be exhausted before an action against the Department or its agencies may be initiated.

Regulatory Flexibility Act Certification

RUS has determined that this final rule will not have significant impact on a substantial number of small entities defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The RUS loan programs provide borrowers with loans at interest rates and terms that are more favorable than those generally available from the private sector. Borrowers, as a result of obtaining federal financing, receive economic benefits that exceed any direct cost associated with RUS regulations and requirements.

National Environmental Policy Act Certification

RUS has determined that this final rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

Catalog of Federal Domestic Assistance

The programs described by this final rule are listed in the Catalog of Federal Domestic Assistance under Numbers CFDA 10.751, Rural Energy Savings Program; CFDA 10.787, Broadband Initiatives Program; CFDA 10.850, Rural Electrification Loans and Loan Guarantees; CFDA 10.851, Rural Telephone Loans and Loan Guarantees; CFDA 10.855, Distance Learning and Telemedicine Loans and Grants; CFDA 10.857, Bulk Fuel Revolving Fund Grants; CFDA 10.858, Denali Commission Grants and Loans; CFDA 10.859, Assistance to High Energy Cost Rural Communities; CFDA 10.861, Public Television Station Digital Transition Grant Program; and, CFDA 10.863, Community Connect Grant Program. The General Services Administration (GSA) website at *http://www.cfda.gov* contains a PDF file version of the CFDA catalog. The print edition of the catalog may be purchased from the U.S. Government Publishing Office (GPO) by calling (202) 512–1800 or toll free at 1–866–512–1800, or by ordering it online at *http://bookstore.gpo.gov.*

Information Collection and Recordkeeping Requirements

The reporting and recordkeeping requirements contained in this final rule have been approved by the Office of

Management and Budget (OMB) under OMB Control Number 0572–0095, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C Chapter 35). This final rule contains no new reporting or recordkeeping burdens under OMB Control Number 0572–0095 that would require approval under the Paperwork Reduction Act.

Send questions or comments regarding this burden or any other aspect of these collections of information, including suggestions for reducing the burden, to Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Stop 1522, Room 5164–S, Washington, DC 20250–1522.

Unfunded Mandates

This final rule contains no Federal mandates (under the regulatory provision of title II of the Unfunded Mandates Reform Act of 1995) for state, local, and tribal governments or the private sector. Thus, this final rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act of 1995.

Comments

We invite you to participate in this rulemaking by submitting written comments, data, or views before the noted deadline. We will consider the comments we received and may conduct additional rulemaking based on the comments.

Background

7 CFR part 1773, Policy on Audits of RUS Borrowers and Grantees (Part 1773), implements the standard RUS security instrument provision requiring RUS electric and telecommunications borrowers and grantees to prepare and furnish to RUS, at least once during each 12-month period, a full and complete report of its financial condition, operations, and cash flows, in form and substance satisfactory to RUS; audited and certified by an independent audit organization, satisfactory to RUS, and accompanied by a report of such audit, in form and substance satisfactory to RUS. This rule is amended to include coverage of all grantees and the title of Part 1773 is revised to reflect this change.

This rule amends Part 1773 to incorporate the 2011 revisions to GAGAS by the GAO issued in December 2011. The 2011 revision contains major changes that reinforce the principles of transparency and accountability and provide the framework for high-quality government audits that add value. This revision to GAGAS incorporates the AICPA Statements on Auditing Standards. The 2011 revisions to GAGAS were effective for financial audits for periods ending on or after December 15, 2012.

The professional standards and guidance contained in GAGAS provide a framework for conducting high quality audits with competence, integrity, objectivity, and independence. These standards are used by auditors of entities that receive government awards and audit organizations performing GAGAS audits. GAGAS contains standards for audits as well as requirements and guidance dealing with ethics, independence, auditors' professional judgment and competence, quality control, performance of the audit, and reporting.

This rule amends Part 1773 to incorporate the clarified audit standards issued by the AICPA in October 2011. The purpose of redrafting the auditing standards was for clarity and convergence although there were some changes and additions in terms of requirements. The clarified standards also introduced new terminology and new audit reports by adding extra paragraphs and segregating sections of the report under subheadings.

In 2013, the Office of Management and Budget (OMB) revised uniform administrative requirements, cost principles, and audit requirements for Federal awards by issuing 2 CFR part 200, which served to consolidate and replace OMB Circulars A–21, A–87, A–89, A–102, A–110, A–122, and A–133. 2 CFR part 200 was adopted by USDA in December 2014. The portion of this CFR applicable to audits, Subpart F, is recognized and adopted by this revision to Part 1773.

This rule revises all subparts to encompass grantees, to remove most references to Rural Telephone Bank (RTB), to conform the language used to generally accepted auditing standards (GAAS) issued by the AICPA and GAGAS. This rule adds, changes or deletes definitions as appropriate to clarify certain existing information. Perhaps most importantly, this rule replaces the RUS management letter with a report on compliance with aspects of contractual agreements and regulatory requirements based on the requirements found in AU–C 806 of GAAS. This rule also provides information on the electronic filing of annual audits in § 1773.21. RUS is also adding a requirement to the reporting package for a schedule of findings and recommendations in § 1773.34.

Due to the state boards of accountancy having now adopted peer review requirements as part of the CPA licensing requirements for performing attestation services, this amended rule significantly streamlines the RUS peer review monitoring included in § 1773.5 by removing much of the guidance previously provided with regard to auditor participation in an approved peer review program. RUS will no longer require that all auditors submit copies of their peer review reports but reserves the right to request said reports on a case by case basis. It also removes the option of requesting a waiver of the peer review requirement, relying instead on the requirements of the state boards of accountancy and the guidance provided within the peer review programs themselves.

Due to the scope and pervasiveness of the revisions being implemented, Part 1773 as revised is being published in its entirety in this final rule.

In this revision to Part 1773, all sample reports and financial statements will be combined into four appendices which will be available in RUS Bulletin 1773–1, Policy on Audits of RUS Borrowers and Grantees. Appendix A of RUS Bulletin 1773–1 contains the sample reports, financial statements and schedule of findings and recommendations for electric borrowers; Appendix B contains similar samples for telecommunications borrowers; Appendix C for broadband borrowers; and Appendix D contains sample reports for grantees. Appendices A through D will not be printed in the Code of Federal Regulations; however, these appendices are available at *https://www.regulations.gov/* for review and comment in conjunction with the comment period for this final rule. Only Subparts A through E will be published in the Code of Federal Regulations. The appendices are included in RUS Bulletin 1773–1, Policy on Audits of RUS Borrowers and Grantees, which contains all of Part 1773, including subparts A through E and the appendices. Publishing Part 1773 in bulletin form provides the RUS audit policy in an easy to read format. This publication is available on RUS' website at *https://www.rd.usda.gov/publications/regulations-guidelines/rural-utilities-service-audit.*

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(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *fax:* (202) 690–7442; or

(3) *email: program.intake@usda.gov.*

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List of Subjects in 7 CFR Part 1773

Accounting, Auditing, Electric power, Grants, Loan programs—broadband, Loan programs—communications, Loan programs—energy, Reporting and recordkeeping requirements, Rural areas, Telephone.

■ For the reasons set forth in the preamble, RUS revises 7 CFR part 1773 to read as follows:

PART 1773—POLICY ON AUDITS OF RUS BORROWERS AND GRANTEES

Subpart A—General Provisions

Sec.

Subpart B—RUS Audit Requirements

Subpart C—RUS Requirements for the Submission and Review of the Reporting Package

Subpart D—RUS Reporting Requirements

Subpart E—RUS Audit Requirements and Documentation

Authority: 7 U.S.C. 901 *et seq.,* 7 U.S.C. 1921 *et seq.,* 7 U.S.C. 6941 *et seq.*

Subpart A—General Provisions

§ 1773.1 General.

(a) This part implements the standards for audits required by the loan and grant agreements of Rural Utilities Service (RUS) electric and telecommunications borrowers and grantees. The provisions require auditees to prepare and furnish to RUS, at least once during each 12-month period, a full and complete report of its financial condition, operations, and cash flows, in form and substance satisfactory to RUS, audited and certified by an independent auditor, satisfactory to RUS, and accompanied by a report of such audit, in form and substance satisfactory to RUS.

(b) This part is based on the requirements of GAGAS in effect at the time of the audit and applicable RUS regulations and subpart F (Audit Requirements) of 2 CFR part 200 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards) (2 CFR 200.500–200.521).

(c) This part further sets forth the criteria for selecting auditors satisfactory to RUS and certain audit procedures and audit documentation that must be performed and prepared before an audit report will be accepted by RUS.

(d) Failure to provide an audit in compliance with this part is a serious violation of the RUS Security Agreement. RUS relies on audited financial statements in order to assess and monitor the financial condition of its borrowers and grantees and to fulfill its fiduciary responsibilities.

(e) RUS reserves the right to suspend its acceptance of audits performed by auditors who, in the opinion of RUS, are not meeting the requirements of this part or with unresolved disputes or issues until such time that the matter can be resolved to RUS' satisfaction.

§ 1773.2 Definitions.

As used in this part:

2 CFR part 200, subpart F means 2 CFR part 200, Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, subpart F, Audit Requirements, as adopted by USDA in 2 CFR part 400.

AA–PARA means RUS Assistant Administrator, Program Accounting and Regulatory Analysis.

Administrator means the Administrator of RUS.

Affiliated company means a company that directly or indirectly through one or more intermediaries, control or are controlled by, or are under common control with, the auditee.

AICPA means the American Institute of Certified Public Accountants.

ASC means the Accounting Standards Codification issued by the Financial Accounting Standards Board.

Audit means an examination of financial statements by an independent auditor for the purpose of expressing an opinion on the fairness with which those statements present financial position, results of operations, and changes in cash flows in accordance with accounting principles generally accepted in the United States of America (GAAP) and for determining whether the auditee has complied with applicable laws, regulations, and provisions of loan or grant contracts and grant agreements that could have a material effect on the financial statements.

Audit date means the ''as of'' date established by the auditee.

Audit documentation has the same meaning as defined in the AICPA's professional auditing standards.

Auditee means an RUS borrower and/or grantee that is required to submit an annual audit as a condition of the award.

Auditor means government auditors as well as certified public accounting firms that perform audits using generally accepted government auditing standards (GAGAS).

BCAS means Broadband Collection and Analysis System (or successor system).

Borrower means an entity that has an outstanding RUS or Federal Financing Bank (FFB) loan or loan guarantee.

CPA means a Certified Public Accountant.

DCS means the Data Collection System (or successor system).

FASB means Financial Accounting Standards Board.

FFB means the Federal Financing Bank, a body corporate and instrumentality of the United States of America under the general supervision of the Secretary of the Department of the Treasury.

Fraud has the same meaning as defined in the AICPA's professional auditing standards.

GAAP has the same meaning as defined in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).

GAGAS means generally accepted government auditing standards as set forth in Government Auditing Standards, issued by the Comptroller General of the United States, Government Accountability Office.

GAO means the United States Government Accountability Office.

GASB means Government Accounting Standards Board.

Governance board means the auditee's board of directors, managing members, or other official body charged with governance.

Grantee means an entity that has a continuing responsibility under a grant agreement with RUS.

Illegal act has the same meaning as defined by the Public Company Accounting Oversight Board.

Material weakness has the same meaning as defined in the AICPA's professional auditing standards.

OIG means the Office of the Inspector General, United States Department of Agriculture.

OMB means The Office of Management and Budget.

Regulatory asset means an asset resulting from an action of a regulator as defined by FASB.

Regulatory liability means a liability imposed on a regulated enterprise by an action of a regulator as defined by FASB.

Related party has the same meaning as defined by FASB.

Reporting package means:

(1) The auditor's report on the financial statements;

(2) The report on internal control over financial reporting and on compliance and other matters;

(3) The report on compliance with aspects of contractual agreements and regulatory requirements;

(4) The schedule of findings and recommendations; and

(5) All supplemental schedules and information required by this part.

RUS means the Rural Utilities Service, an agency of the United States Department of Agriculture.

RUS Bulletin 1773–1, Policy on Audits of RUS Borrowers and Grantees, is a publication prepared by RUS that contains the RUS regulation 7 CFR part 1773 and exhibits of sample audit reports, financial statements, reports on internal control over financial reporting and on compliance and other matters, report on compliance with aspects of contractual agreements and regulatory requirements, and schedule of findings and recommendations used in preparing audits of RUS borrowers and grantees. This bulletin is available on the internet at *https://www.rd.usda.gov/publications/regulations-guidelines/bulletins/program-accounting.*

RUS security agreement means a loan agreement, grant agreement, mortgage, security agreement, or other form of agreement that governs the terms and conditions of, or provides security for, loan and/or grant funds provided by RUS to the auditee.

Significant deficiency has the same meaning as defined in the AICPA's professional auditing standards.

Single Audit Act means Single Audit Act of 1984 (31 U.S.C. 7501 *et seq.*) as implemented by 2 CFR part 200, subpart F.

State means any state or territory of the United States, or the District of Columbia.

Uniform System of Accounts means, for telecommunications borrowers, Bulletin 1770B–1, Accounting Requirements for RUS Telecommunications Borrowers (*https://www.rd.usda.gov/files/UTP_Bulletins_1770B-1.pdf*), and for electric borrowers, as contained in 7 CFR part 1767, Accounting Requirements for RUS Electric Borrowers, subpart B—Uniform System of Accounts, Bulletin 1767B–1, (*https://www.rd.usda.gov/files/UPA_Bulletin_1767B-1.pdf*).

Subpart B—RUS Audit Requirements

§ 1773.3 Annual audit.

(a) Each auditee must have its financial statements audited annually by an auditor selected by the auditee and approved by RUS as set forth in § 1773.4. All auditees must submit audited financial statements on a comparative basis covering two consecutive 12 month periods, unless the entity has not been in existence for two consecutive 12-month audit periods. Consolidated statements of the parent are not an acceptable replacement for an audit of the auditee.

(b) Each auditee must establish an annual audit date within 12 months of the date of the first advance and must prepare annual financial statements for the audit date established. Each auditee must notify the AA–PARA of the audit date at least 90 days prior to the selected audit date.

(c) Auditees must furnish a reporting package to RUS within 120 days of the audit date. (See § 1773.21). Until all loans made or guaranteed by RUS are repaid and unliquidated obligations rescinded, auditees that are borrowers must continue to provide annual audited financial statements. Auditees that are grantees must furnish annual audited financial statements in the year of the first advance and until all funds have been advanced or rescinded, and all financial compliance requirements have been fully satisfied.

(d) In addition to the requirements of this part, certain auditees may be subject to the Single Audit Act. An auditee that is defined as a Non-Federal Entity as defined in 2 CFR 200.69 means a state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient and is required to meet the requirements of this part as follows:

(1) Borrowers and/or grantees expending the threshold established for the Single Audit Act (currently $750,000) or more in Federal awards during the year must have an audit performed in accordance with the Single Audit Act. See 2 CFR 200.502, Basis For Determining Federal Awards Expended, for guidance in determining annual expenditures. The audited financial statements must be submitted to RUS and to the Federal Audit Clearinghouse.

(2) For auditees expending less than the threshold for expenditure in Federal awards during the year, RUS reserves its right under 2 CFR 200.503, Relationship to other audit requirements, to arrange for an audit performed in accordance with this part.

(3) Within 30 days of the audit date, auditees must notify the AA–PARA, in writing, of the total Federal awards expended during the year and must state whether the audit will be performed in accordance with the Single Audit Act, or this part.

(i) An auditee electing to comply with this part must select an auditor that meets the qualifications set forth in § 1773.5.

(ii) If an audit is performed in accordance with the Single Audit Act, the auditor's reporting on the financial statements that meet the requirements of the Single Audit Act, will be sufficient to satisfy the auditee's obligations under this part.

(e) Subpart F of 2 CFR part 200 does not apply to audits of RUS electric and telecommunications cooperatives and for-profit telecommunications borrowers unless the borrower has contractually agreed with another Federal agency (*e.g.* Federal Emergency Management Agency) to provide a financial audit performed in accordance with 2 CFR part 200, subpart F. In no circumstance will an auditee be required to submit separate audits performed in accordance with this part and 2 CFR part 200, subpart F.

§ 1773.4 Auditee's responsibilities.

(a) *Selection of a qualified auditor.* The auditee's governance board is responsible for the selection of a qualified auditor that meets the requirements set forth in § 1773.5. When selecting an auditor, the auditee should consider, among other matters:

(1) The qualifications of auditors available to do the work;

(2) The auditor's experience in performing audits of utilities, related industries, or in the case of grantees, experience in auditing entities comparable to the grantee; and

(3) The auditor's ability to complete the audit and submit the reporting package within 90 days of the audit date.

(b) *Board approval of selection.* The board's approval of an auditor must be recorded by a board resolution that states:

(1) The auditor represents that it meets RUS qualifications to perform an audit; and

(2) The auditee and auditor will enter into an audit engagement in accordance with § 1773.6.

(c) *Notification of selection.* When the initial selection or subsequent change of an auditor has been made, the auditee must notify the AA–PARA, in writing, at least 90 days prior to the audit date.

(1) Within 30 days of the date of receipt of such notice, RUS will notify the auditee, in writing, if the selection or change in auditor is not satisfactory.

(2) Notification to RUS that the same auditor has been selected for succeeding audits of the auditee's financial statements is not required; however, the procedures outlined in this part must be followed for each new auditor selected, even though such auditor may previously have been approved by RUS to audit records of other RUS auditees. Changes in the name of an auditor are considered to be a change in the auditor.

(d) *Audit engagement letter.* The auditee must enter into an audit agreement with the auditor that complies with § 1773.6 prior to the initiation of the audit.

(e) *Debarment certification.* The auditee must obtain, from the selected auditor, a lower tier covered transaction certification (Form AD–1048, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions), as required by Executive Orders 12549 and 12689, Debarment and Suspension, and any rules or regulations issued thereunder.

(f) *Peer review report.* The auditee must obtain, from the selected auditor, a copy of the auditor's current approved peer review report.

(g) *Preparation of schedules.* The auditee must prepare any schedules that are required by the auditor to perform the audit, including a schedule of deferred debits and deferred credits and a detailed schedule of investments in subsidiary and affiliated companies accounted for on the cost, equity, or consolidated basis. The detailed schedule of investments can be included in the notes to the financial statements or as a separate schedule as long as all information required is adequately disclosed. Samples of these schedules can be found in Appendices A–D, of RUS Bulletin 1773–1.

(1) The schedule of deferred debits and deferred credits must include a description of the deferral and a notation as to whether the deferral has received written approval from RUS. If a determination is made that prior written approval is not required, cite the specific authority for the deferral.

(2) The schedule of investments must include investments in subsidiary and affiliated companies, corporations, limited liability corporations and partnerships, joint ventures, etc. accounted for on either the cost, equity or on a consolidated basis. For all investments, the auditee must list the name of the entity, ownership percentage, and the principal business in which the entity is engaged. For investments recorded on the cost basis, the auditee must include the original investment, advances, dividends declared or paid in the current and prior years and the net investment. For investments recorded on the equity or consolidated basis, the auditee must include the ownership percentage, original investment, advances, dividends declared or paid in the current and prior years, and current and prior years' earnings and losses, including accumulated losses in excess of the original investment.

(h) *Scope limitations.* The auditee will not limit the scope of the audit to the extent that the auditor is unable to provide an unqualified opinion that the financial statements are presented fairly in conformity with GAAP due to the scope limitation.

(i) *Submission of reporting package.* The auditee must submit to RUS the required reporting package as set forth in § 1773.21.

(1) A reporting package that fails to meet the requirements detailed in this part will be returned to the auditee with a written explanation of noncompliance.

(2) The auditee must, within 30 days of the date of the letter or email detailing the noncompliance, submit a corrected reporting package to RUS.

(3) If a corrected reporting package is not received within 30 days of the date of the letter or email detailing the noncompliance, RUS will take appropriate action, depending on the severity of the noncompliance.

(j) *Submission of a plan of corrective action.* If the auditor's report contains findings and recommendations but does not include the auditee's response, the auditee must submit written responses to RUS within 180 days of the audit date. The written responses must address:

(1) The corrective action already taken or planned, or the reason the auditee believes no action is necessary; and

(2) The status of corrective action taken on previously reported findings and recommendations.

§ 1773.5 Qualifications of the auditor.

Auditors that meet the qualifications criteria of this section and enter into an audit engagement with the auditee that complies with § 1773.6, will be considered satisfactory to RUS.

(a) *Licensing.* Auditors that audit the financial statements of an RUS auditee must be licensed to perform attestation engagements in the United States of America. Auditors do not have to be licensed by the state in which the auditee is located; however, auditors must abide by the rules and regulations of professional conduct promulgated by

the accountancy board of the state in which the auditee is located.

(b) *Independence.* Auditors must be independent as determined by the standards for independence in the AICPA Code of Professional Conduct and in GAGAS in effect at the time of the audit.

(c) *Peer review requirement.* Auditors must be enrolled and participating in a peer review program, and must have undergone a satisfactory peer review of their accounting and audit practice. The peer review must be in effect at the date of the audit report opinion.

(1) *Peer review reports.* RUS reserves the right to request peer review reports from selected auditors.

(2) *Peer review requirements for new auditors.* New auditing firms must meet the requirements of their state board of accountancy with regard to enrolling in a peer review program, timing of the first peer review, and any other peer review requirements.

§ 1773.6 Auditor communication.

(a) GAGAS and AICPA standards require that the auditor communicate with the auditee the auditor's understanding of the services to be performed and document that understanding through a written communication to those charged with governance. To be acceptable to RUS, the auditor's communication must take the form of an audit engagement letter prepared by the auditor and must be formally accepted by the governance board or an audit committee representing the governance board. In addition to the requirements of the AICPA's professional auditing standards and GAGAS, the engagement letter must also include the following:

(1) The nature of planned work and level of assurance to be provided related to internal control over financial reporting and compliance with laws, regulation, and provision of contracts or grant agreements;

(2) That the auditee and auditor acknowledge that the audit is being performed and that the reporting package is being issued to enable the auditee to comply with the provisions of RUS's security instrument which requires compliance with this part;

(3) That the auditor acknowledges the mandatory reporting requirements for fraud, illegal acts, or noncompliance with provisions of laws, regulations, contracts, and grant agreements in § 1773.9. Acceptance of the engagement letter by the auditee is required, thus granting the auditor permission to directly notify the appropriate officials which may include but is not limited to the governance board, RUS, and OIG;

(4) That the auditor acknowledges that it is required under § 1773.7 to contact RUS if the auditor is unable to resolve scope limitations imposed by the auditee, or if such limitations in scope violate this part. Acceptance of the engagement letter by the auditee is required, thus granting the auditor permission to directly notify the AA–PARA as needed;

(5) That the auditee and auditor acknowledge that RUS will consider the auditee to be in violation of its RUS Security Agreement and this part if the auditee fails to have an audit performed and documented in compliance with GAGAS and this part;

(6) That the auditor represents that it meets the requirements under this part to perform the audit;

(7) That the auditor will perform the audit and will prepare the reporting package in accordance with the requirements of this part;

(8) That the auditor will document the audit work performed in accordance with GAGAS, and the requirements of this part; and

(9) That the auditor will make all audit documentation, including the reporting package available to RUS or its representatives (including but not limited to OIG and GAO), upon request, and will permit the photocopying of all such audit documentation.

(b) A copy of the audit engagement letter must be available at the auditee's office for inspection by RUS personnel. One copy of the current audit engagement letter must be maintained in the auditor's audit documentation.

§ 1773.7 Audit standards.

(a) The audit of the financial statements must be performed in accordance with GAGAS and this part in effect at the audit date unless the auditee is directed otherwise, in writing, by RUS.

(b) The audit of the financial statements must include such tests of the accounting records and such other auditing procedures that are sufficient to enable the auditor to express an opinion on the financial statements and to issue the required reporting package.

(c)(1) The auditee will not limit the scope of the audit to the extent that the auditor is unable to meet RUS audit requirements without prior written approval of the AA–PARA.

(2) If the auditor determines during the audit that an unqualified opinion cannot be issued due to a scope limitation imposed by the auditee, the auditor should use professional judgment to determine what levels of the auditee's management and/or those charged with governance should be informed.

(3) After informing the auditee's management and/or those charged with governance, if the scope limitation is not adequately resolved, the auditor should immediately contact the AA–PARA.

§ 1773.8 Audit date.

(a) The annual audit must be performed as of the end of the same calendar month each year unless prior approval to change the audit date is obtained, in writing, from RUS.

(1) An auditee may request a change in the audit date by writing to the AA–PARA at least 60 days prior to the currently approved audit date, providing justification for the change.

(2) The time period between the prior audit date and the newly requested audit date must be no longer than twenty-three months.

(3) Comparative financial statements must be prepared and audited for the 12 months ending as of the new audit date and for the 12 months immediately preceding that period.

§ 1773.9 Disclosure of fraud, and noncompliance with provisions of laws, regulations, contracts, and loan and grant agreements.

(a) In accordance with GAGAS, the auditor is responsible for planning and performing the audit to provide reasonable assurance about whether the financial statements are free of material misstatement due to error or fraud. The auditor must also plan the audit to provide reasonable assurance of detecting material misstatements resulting from violations of provisions of laws, regulations, contracts or loan and grant agreements that could have a direct and material effect on the financial statements.

(b) If specific information comes to the auditor's attention that provides evidence concerning the existence of possible violations of provisions of laws, regulations, contracts or loan and grant agreements that could have a material indirect effect on the financial statements, the auditor should apply audit procedures specifically directed to ascertaining whether a violation of provisions of laws, regulations, contract or grant agreements has occurred.

(c) Pursuant to the terms of its audit engagement letter with the auditee, the auditor must immediately report, in writing, all instances of fraud, illegal acts, and all indications or instances of noncompliance with laws, whether material or not, to:

(1) The president of the auditee's governance board;

(2) AA–PARA; and
(3) OIG, as follows:
(i) For all audits performed in accordance with § 1773.3(d) (audits conducted in accordance with 2 CFR part 200 ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards''), report to the USDA–OIG-Audit, National Single Audit Coordinator for USDA, 401 W. Peachtree St NW, Room 2328, Atlanta, GA 30308,
(ii) For all other audits conducted in accordance with § 1773.3 report to the appropriate office based on location. See *https://www.usda.gov/oig/national.htm* to determine the correct reporting location.

§ 1773.10 Access to audit documentation.

Pursuant to the terms of this part and the audit engagement letter, the auditor must make all audit documentation available to RUS, or its designated representative, upon request and must permit RUS, or its designated representative, to photocopy all audit documentation.

§§ 1773.11–1773.19 [Reserved]

Subpart C—RUS Requirements for the Submission and Review of the Reporting Package

§ 1773.20 The auditor's submission of the reporting package.

(a) *Time limit.* Within 90 days of the audit date, the auditor must deliver the reporting package to the auditee's governance board. At a minimum, copies should be provided for each member of the governance board and the manager. The auditor must also provide an electronic copy of the audit which meets the requirements of § 1773.21 for subsequent transmittal to RUS.

(b) *Communication with the governance board.* In addition to providing sufficient copies of the reporting package for each member of the auditee's governance board, RUS requires that the auditor report all audit findings to the auditee's governance board. RUS recommends that audit findings also be communicated orally unless oral communication would not be adequate. If the information is communicated orally, the auditor must document the communication by appropriate memoranda or notations in the audit documentation. If the auditor communicates in writing, a copy of the written communication must be included in the auditor's audit documentation.

(c) *Matters to be communicated.* Matters communicated to those charged with governance must include, but are not limited to the matters to be communicated as prescribed in the AICPA's professional standards AU–C Section 260, ''The Auditor's Communication with Those Charged with Governance''.

§ 1773.21 Auditee's review and submission of the reporting package.

(a) The auditee's governance board should note and record receipt of the reporting package and any action taken in response to the reporting package in the minutes of the board meeting at which such reporting package is presented.

(b) The auditee must furnish RUS with an electronic copy of the reporting package within 120 days of the audit date as provided for in § 1773.3.

(c) The auditee must furnish AA–PARA with a copy of its plan for corrective action, if any, within 180 days of the audit date.

(d) The auditee must include in the reporting package a copy of each special report, summary of recommendations or similar communications, if any, received from the auditor as a result of the audit.

(e) All required submissions to RUS described in paragraphs (b) through (d) of this section should be furnished electronically. The electronic copy must be provided in a Portable Document Format (PDF). Auditees with a designation from 0001 through 0199 in the Electric program and 500 through 699 in the Telecommunications programs shall upload the reporting package to the DCS or its successor system. Borrowers and/or grantees with a designation from 1100 through 1199, 1300 through 1399, and 1400 through 1499 in the Broadband program shall upload the reporting package to the BCAS or its successor system. All other borrowers and/or grantees may upload their reporting package through DCS or its successor system. Specific instructions for submission are available from the Technical Accounting and Auditing Staff.

§§ 1773.22–1773.29 [Reserved]

Subpart D—RUS Reporting Requirements

§ 1773.30 [Reserved]

§ 1773.31 Auditor's report on the financial statements.

The auditor must prepare a written report on comparative balance sheets, statements of revenue and patronage capital (or statement of operations customary to the type of entity reporting) and statements of cash flows. The report must include the manual or printed signature of the auditor, cover all statements presented, and refer to the separate report on internal controls over financial reporting and on compliance and other matters and the report on compliance with aspects of contractual agreements and regulatory requirements issued in conjunction with the auditor's report on the financial statements. The auditor's report on the financial statements should also state that the report on internal controls over financial reporting and on compliance and other matters is an integral part of a GAGAS audit, and in considering the results of the audit, that this report should be read along with the auditor's report on the financial statements.

§ 1773.32 Report on internal control over financial reporting and on compliance and other matters.

(a) As required by GAGAS, the auditor must prepare a written report describing the scope of the auditor's testing of internal control over financial reporting and of compliance with provisions of laws, regulations, contracts, and loan and grant agreements, and that the tests provided sufficient, appropriate evidence to support opinions on the effectiveness of internal control and on compliance with provisions of laws, regulations, contracts, and loan and grant agreements. This report must include the manual or printed signature of the auditor and must include the following items as appropriate:
(1) Significant deficiencies and material weaknesses in internal control;
(2) Instances of fraud and noncompliance with provisions of laws or regulations that have a material effect on the audit and any other instances that warrant the attention of those charged with governance;
(3) Noncompliance with provisions of contracts or grant agreements that have a material effect on the audit; and
(4) Abuse that has a material effect on the audit.

(b) When the auditor detects instances of noncompliance or abuse that have an effect on the financial statements that are less than material but warrant the attention of those charged with governance, they should communicate those findings in writing to those charged with governance in a separate communication. If the auditor has issued a separate communication detailing immaterial instances of noncompliance or abuse, the report on internal controls over financial reporting and on compliance and other matters must be modified to include a statement such as:

''We noted certain immaterial instances of noncompliance [and/or abuse], which we have reported to the management of (auditee's name) in a separate letter dated (month, day, 20XX).''

(c) If the auditor has issued a separate letter to management to communicate other matters involving the design and operation of the internal control over financial reporting, the report on internal controls over financial reporting and on compliance and other matters must be modified to include a statement such as:

''However, we noted other matters involving the internal control over financial reporting that we have reported to the management of (auditee's name) in a separate letter dated (month, day, 20XX).''

(d) The report must contain the status of known but uncorrected deficiencies from prior audits that affect the current audit objective.

§ 1773.33 Report on compliance with aspects of contractual agreements and regulatory requirements.

The auditor must prepare a report on compliance with aspects of contractual agreements and regulatory requirements that includes, at a minimum, comments on:

(a) *Audit procedures.* State whether the audit has been performed in accordance with this part;

(b) *Special reports.* State whether any special reports, summaries of recommendations, or similar communications were furnished to the auditee's management during the course of the audit or during interim audit work, and provide a description of the information furnished;

(c) *Accounting and records.* Comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the auditee did not maintain adequate and effective accounting procedures and records and utilize adequate and fair methods for accumulating and recording labor, material, and overhead costs, and for distributing these costs to construction, retirement, and maintenance or other expense accounts. Where appropriate, comment on whether anything came to the auditor's attention to indicate that the auditee did not:

(1) Establish continuing property records (CPRs) that are updated on a current basis, at least annually, and are reconciled with the controlling general ledger plant accounts;

(2) Promptly clear construction clearing accounts of costs of completed construction to the proper classified plant accounts and accrue depreciation on such completed construction from the date the plant was placed in service;

(3) Currently and systematically record and properly price retirements of plant;

(4) Properly account for the accumulated provision for depreciation accounts associated with retirements of plant or properly disclose any unusual charges or credits to such accounts; and

(5) Obtain RUS approval for the sale, lease or transfer of capital assets secured under the RUS security agreement when approval is required, and properly handle any proceeds from the sale or lease of plant, material or scrap in conformance with RUS requirements.

(d) *Materials control.* Comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the control over materials and supplies was not adequate.

(e) *Compliance with RUS loan and security instrument provisions.* Comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the following provisions of RUS' loan and security instruments have not been complied with:

(1) For electric auditees, provisions related to:

(i) The requirements for an auditee to obtain written approval of mortgagees to enter into any contract for the management, operation, or maintenance of the auditee's system if the contract covers all or substantially all of the electric system. For purposes of this part, the following contracts shall be deemed as requiring RUS approval:

(A) Management contracts in which the auditee has contracted to have another auditee or other entity manage its affairs;

(B) Operations and maintenance contracts in which the auditee has contracted to have another auditee or other entity operate and/or maintain all or substantially all of the physical plant facilities of the auditee.

(C) Operations and maintenance contracts in which the auditee has contracted to operate and maintain the physical plant facilities of another auditee or other utility system;

(ii) The requirement for an auditee to prepare and furnish mortgagees annual or periodic financial and operating reports on the auditee's financial condition and operations accurately and within the required deadlines. The auditor shall comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the information represented by the auditee as having been submitted to RUS in its most recent December 31 Financial and Operating Report Electric Distribution or Financial and Operating Report Electric Power Supply was not in agreement with the auditee's audited records. If the auditee represents that an amended report has been filed as of December 31, the comments must relate to the amended report; and

(iii) The requirement for an auditee to use depreciation rates that are within the ranges established by RUS for each primary plant account (See RUS Bulletin 183–1, Depreciation Rates and Procedures *at https://www.rd.usda.gov/files/UPA_Bulletin_183-1.pdf*), or with the requirements of the state regulatory body having jurisdiction over the auditee's depreciation rates in computing monthly accruals.

(2) For telecommunications auditees, provisions related to:

(i) The requirement for an auditee to obtain written approval of the mortgagees to enter into any contract, agreement or lease between the auditee and an affiliate other than as allowed under 7 CFR part 1744, subpart E; and

(ii) The requirement for an auditee to prepare and furnish mortgagees annual or periodic financial and operating reports on the auditee's financial condition and operations accurately and within the required deadlines. The auditor shall comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the information represented by the auditee as having been submitted to RUS in its most recent December 31 Operating Report for Telecommunications Borrowers was not in agreement with the auditee's audited records. If the auditee represents that an amended report has been filed as of December 31, the comments must be related to the amended report.

(3) For Broadband auditees, provisions relating to the requirement for an auditee to prepare and furnish mortgagee quarterly or periodic financial and operating reports on the auditee's financial condition and operations accurately and within the required deadlines. The auditor shall comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the information represented by the auditee as having been submitted to RUS in its most recent BCAS filing was not in agreement with the auditee's audited records. If the auditee represents that an amended report has been filed, the comments must be related to the amended report.

(4) For grantees, provisions related to:

(i) Recipients of Broadband Initiatives Program loans and grants, the requirement for the recipient to prepare and furnish RUS quarterly and annual financial and operating reports on the financial condition and operations of the auditee accurately and within the required deadlines. The auditor shall comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the information represented by the auditee as having been submitted to RUS in its most recent BCAS filing was not in agreement with the audited records of the auditee. If the auditee represents that an amended report has been filed, the comments must relate to the amended report. The auditor must state whether the Annual Compliance Certificate required by the RUS Security Agreement has been filed in a timely manner with RUS.

(ii) Recipients of all other grant programs within the electric and telecommunications programs, the requirements to prepare and furnish RUS with any required financial reporting accurately and within required deadlines, as appropriate for that specific program. The auditor shall comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the information represented by the grantee as having been submitted to RUS in its most recent filing was not in agreement with the audited records of the grantee. If the grantee represents that an amended report has been filed, the comments must relate to the amended report.

(f) *Related party transactions.* Comment on whether, during the course of the audit, anything came to the attention of the auditor to indicate that all material related party transactions have not been disclosed in the notes to the financial statements in accordance with ASC 850, entitled ''Related Party Disclosures''.

(g) *Deferred debits and deferred credits.* For electric auditees, comment on whether, during the course of the audit anything came to the attention of the auditor to indicate that the auditee provided detailed schedule of deferred debits and deferred credits, including, but not limited to, margin stabilization plans, revenue deferral plans, and expense deferrals is not accurately presented. This schedule must be included as supplemental information or within the notes to the financial statements; and

(h) *Investments.* For electric and telecommunications auditees, comment on whether, during the course of the audit, anything came to the auditor's attention to indicate that the auditee provided detailed schedule of investments is not accurately presented. This schedule must be included as supplemental information or within the notes to the financial statements. The auditor must state that the audit did not disclose any investments in subsidiary or affiliated companies.

§ 1773.34 Schedule of findings and recommendations.

The auditor must prepare a schedule of findings and recommendations to be included with the audited financial statements. The schedule of findings and recommendations shall be developed and presented utilizing the elements of a finding discussed in GAGAS and shall include recommendations for remediation. If the schedule does not include responses from management, as well as any planned corrective actions, those items must be submitted directly to the AA–PARA by management in accordance with § 1773.4(j).

§§ 1773.35–1773.37 [Reserved]

Subpart E—RUS Audit Requirements and Documentation

§ 1773.38 Scope of engagement.

The audit requirements set forth in § 1773.39 through 1773.45 must be met annually by the auditor during the audit of the RUS auditee's financial statements. The auditor must exercise professional judgment in determining whether any auditing procedures in addition to those mandated by GAGAS or this part should be performed on the auditee's financial records in order to afford a reasonable basis for rendering the auditor's report on the financial statements, report on internal controls over financial reporting and on compliance and other matters, report on compliance with aspects of contractual agreements and regulatory requirements, and schedule of findings and recommendations.

§ 1773.39 Utility plant and accumulated depreciation.

(a) *General.* The audit of these accounts shall include tests of additions, replacements, retirements, and changes. The auditor's audit documentation shall support that the auditor:

(1) Examined direct labor and material transactions to determine whether the auditee's accounting records reflect a complete accumulation of costs;

(2) Examined indirect costs and overhead charges to determine if they conform to the Uniform System of Accounts or the Federal Acquisitions Regulations as required under the RUS Security Agreement;

(3) Reviewed the costs of completed construction and retirement projects to determine if they were cleared promptly from the work in progress accounts to the classified plant in service accounts and the related depreciation accounts;

(4) Examined direct purchases of special equipment and general plant;

(5) Determined the degree of accuracy and control of costing retirements, including tests of salvage and removal costs;

(6) Reviewed the auditee's work order procedures; and

(7) Reviewed depreciation rates for adequate support, and compared them to RUS guidelines to determine that they were in compliance.

(b) *Construction work in progress.* (1) The audit documentation shall include a summary of open work orders reconciled to the general ledger and note on the summary any unusual or atypical projects.

(2) The auditor's audit documentation shall support that the auditor:

(i) Reviewed equipment purchases charged to work orders, including payments and receiving reports;

(ii) Reviewed contracts showing the scope of the work, the nature of the contract, the contract amount, and scheduled payments and reviewed supporting documents to determine that services contracted for were in fact rendered;

(iii) Reviewed time cards and pay rates for a sample of employees who allocate their time to work orders;

(iv) Reviewed the nature of material and supplies issued to the project, traced amounts and quantities to supporting documents, and reviewed the reasonableness of clearing rates for assignment of stores expense to the work order;

(v) Reviewed the accuracy of the computation of overheads applied to the work order; and

(vi) Reviewed other costs charged to the work order for support and propriety.

(3) The auditor's audit documentation shall support that the auditor:

(i) Scheduled payments to contractors and traced to verify payments and supporting invoices;

(ii) Traced contract costs to final closeout documents, to the general ledger, and to the continuing property records; and

(iii) Verified the costs of owner furnished materials, if applicable.

(4) The auditor shall review the auditee's procedures for unitization and classification of work order and contract

costs. The auditor's audit documentation shall support that the auditor:

(i) Reviewed the tabulation of record units for construction from the work order staking sheets to the tabulation of record units, to the unitization sheets, and to the continuing property records;

(ii) Reviewed the procedures for unitizing and distributing costs of completed construction to the plant accounts;

(iii) Verified that standard costs were being used;

(iv) Evaluated the basis for development of standard costs; and

(v) Determined that costs of completed construction were cleared promptly from work in progress accounts.

(c) *Continuing property records.* The auditor's audit documentation shall support that the auditor:

(1) Determined whether the subsidiary plant records agree with the controlling general ledger plant accounts;

(2) Noted differences in the audit documentation; and

(3) Commented, in the report on compliance with aspects of contractual agreements and regulatory requirements, on any discrepancies.

(d) *Retirement work-in-progress.* The auditor's audit documentation shall support that the auditor:

(1) Determined that plant retirements are currently and systematically recorded and priced on the basis of the continuing property records, and determined that costs of removal have been properly accounted for;

(2) Explained the method used in computing the cost of units of plant retired if continuing property records have not been established and determined whether costs appeared reasonable; and

(3) Determined the manner in which net losses due to retirements were accounted for and traced clearing entries to the depreciation reserve, the plant accounts, and the continuing property records.

(e) *Provision for accumulated depreciation.* The auditor's audit documentation shall support that the auditor:

(1) Verified the depreciation accruals for the period, including the depreciation base;

(2) Reviewed the basis of the depreciation rates, any change in rates and the reason for the change, and, if appropriate, determined whether the rates are in compliance with RUS requirements or with the requirements of the state regulatory body having jurisdiction over the auditee's depreciation rates;

(3) Reviewed salvage and removal costs; and

(4) Searched for unrecorded retirements.

(f) *Other reserves.* The auditor's audit documentation shall include an account analysis for all other material plant reserves, such as the reserve for the amortization of plant acquisition adjustments. The auditor's audit documentation shall support that appropriate tests of transactions were performed.

(g) *Narrative.* The auditor shall include in the audit documentation a comprehensive narrative on the scope of work performed, observations made, and conclusions reached. Matters covered in this narrative shall include:

(1) The nature of construction and other additions;

(2) The control over, and the accuracy of pricing retirements;

(3) The accuracy of distributing costs to classified utility plant accounts;

(4) An evaluation of the method of:

(i) Capitalizing the direct loadings on labor and material costs;

(ii) Distributing transportation costs and other expense clearing accounts; and

(iii) Capitalizing overhead costs;

(5) The tests of depreciation;

(6) A review of agreements such as those relating to acquisitions, property sales, and leases which affect the plant accounts; and

(7) Notations, if applicable, of RUS approval of property sales and the propriety of the disposition of the proceeds.

§ 1773.40 Regulatory assets.

The auditor's audit documentation shall support that the auditor tested whether all regulatory assets comply with the requirements of ASC 980. For Electric auditees only, the auditor's audit documentation shall support that all regulatory assets have received RUS approval.

§ 1773.41 Extraordinary retirement losses.

The auditor's audit documentation shall support that the auditor tested retirement losses, including any required approval by a regulatory commission with jurisdiction in the matter, or RUS, in the absence of commission jurisdiction.

§ 1773.42 Clearing accounts.

The auditor's audit documentation shall support that the auditor tested all clearing accounts and that transactions selected for testing were reviewed for proper allocation between expense and capital accounts.

§ 1773.43 Capital and equity accounts.

(a) *Capital stock.* For privately owned companies, the audit documentation shall include analyses of all stock transactions during the audit period. The auditor's audit documentation shall support that the auditor:

(1) Reviewed the subsidiary records and reconciled them to the general ledger control account;

(2) Reviewed authorizations and issuances or redemptions of capital stock for proper approvals by the governance board, stockholders, regulatory commissions and RUS, as required;

(3) Determined that transactions were made in accordance with the appropriate provisions of the articles of incorporation, bylaws, and RUS loan documents; and

(4) Determined that transactions were recorded in accordance with the Uniform System of Accounts.

(b) *Memberships.* For cooperative organizations, the audit documentation shall include an analysis of the membership transactions during the audit period. The auditor's audit documentation shall support that the auditor:

(1) Reviewed the subsidiary records and reconciled them to the general ledger control account; and

(2) Determined that transactions were made in accordance with the appropriate provisions of the articles of incorporation, bylaws, and RUS loan documents.

(c) *Patronage capital, retained earnings, margins, and other equities.* The audit documentation shall include an analysis of the patronage capital, retained earnings, margins and other equities, and any related reserve accounts. The auditor's audit documentation shall support that the auditor:

(1) Determined that the transactions were made in accordance with the appropriate provisions of the articles of incorporation, bylaws, RUS loan documents, Uniform System of Accounts, or orders of regulatory commissions;

(2) Traced payments to underlying support; and

(3) Determined whether, under the terms of the RUS security instrument, restrictions of retained earnings or margins are required and, if so, whether they have been properly recorded.

§ 1773.44 Long-term debt.

The auditor's audit documentation shall support that the auditor:

(a) Confirmed RUS, FFB, and RTB debt to the appropriate confirmation schedule (RUS Form 690, Confirmation

Schedule Obligation to the FFB; Form 614, Confirmation Schedule—Long-term Obligation to RUS; or, Confirmation Schedule for RTB Debt);

(b) Confirmed other long-term debt directly with the lender;

(c) Examined notes executed or cancelled during the audit period; and

(d) Tested accrued interest computations.

§ 1773.45 Regulatory liabilities.

The auditor's audit documentation shall support that all regulatory liabilities comply with the requirements of ASC 980. For electric auditees only, the auditor's audit documentation shall document whether all regulatory liabilities have received RUS approval.

§§ 1773.46–1773.48 [Reserved]

§ 1773.49 OMB Control Number.

The information collection requirements in this part are approved by the Office of Management and Budget (OMB) and assigned the OMB Control Number 0572–0095.

Date: April 30, 2018.

Kenneth L. Johnson,

Administrator, Rural Utilities Service.

[FR Doc. 2018–09501 Filed 5–4–18; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

RIN 3245–AG79

Debt Refinancing in 504 Loan Program

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: This rule finalizes the interim final rule (IFR) that was published on May 25, 2016, to implement the debt refinancing program reauthorized by Section 521 of Division E of the Consolidated Appropriations Act, 2016. In response to comments received on the IFR, this final rule makes some additional revisions to the program's regulations with respect to the definition of Qualified debt, the requirements related to Eligible Business Expenses, the refinancing of Projects involving single or limited use properties, and the disbursement period.

DATES: This rule is effective June 6, 2018.

FOR FURTHER INFORMATION CONTACT: Linda Reilly, 504 Program Chief at *linda.reilly@sba.gov* or 202–205–9949.

SUPPLEMENTARY INFORMATION:

I. Background Information

The 504 Loan Program is an SBA financing program authorized under Title V of the Small Business Investment Act of 1958 (the ''SBIAct''), 15 U.S.C. 695 *et seq.* The core mission of the 504 Loan Program is to provide long-term financing to small businesses for the purchase or improvement of land, buildings, and major equipment, in an effort to facilitate the creation or retention of jobs and local economic development. Under the 504 Loan Program, loans are made to small business applicants by Certified Development Companies (''CDCs''), which are certified and regulated by SBA to promote economic development within their community. In general, a project in the 504 Loan Program (a ''504 Project'') includes: A loan obtained from a private sector lender with a senior lien covering at least 50 percent of the project cost; a loan obtained from a CDC (a ''504 Loan'') with a junior lien covering up to 40 percent of the total cost (backed by a 100 percent SBA-guaranteed debenture); and a contribution from the Borrower of at least 10 percent equity.

The Small Business Jobs Act of 2010 (the ''Jobs Act''), Public Law 111–240, 124 Stat. 2504, enacted on September 27, 2010, temporarily expanded the ability of a small business to use the 504 Loan Program to refinance certain qualifying debt. Prior to the Jobs Act, a 504 Project could include a refinancing component only if the project involved an expansion of the small business and the existing indebtedness did not exceed 50% of the project cost of the expansion. *See* 13 CFR 120.882(e). The temporary Jobs Act program authorized the use of the 504 Loan Program for the refinancing of debt where there is no expansion of the small business concern (the ''Debt Refinancing Program''). That program expired on September 27, 2012.

Section 521 of Division E of the Consolidated Appropriations Act, 2016 (the ''2016 Act''), Public Law 114–113, enacted on December 22, 2015, reauthorized the Debt Refinancing Program with three modifications:

(1) The Debt Refinancing Program shall be in effect only in those fiscal years during which the cost to the Federal Government of making guarantees under the Debt Refinancing Program and under the 504 Loan Program is zero;

(2) A CDC is required to limit its financings under the 504 Loan Program so that, during any fiscal year, new financings under the Debt Refinancing Program do not exceed 50% of the dollars the CDC loaned under the 504 Loan Program during the previous fiscal year. The 2016 Act provides that this limitation may be waived by SBA upon application by a CDC and after determining that the refinance loan is needed for good cause; and

(3) The alternate job retention goal authorized by the Jobs Act for the Debt Refinancing Program is eliminated.

On May 25, 2016, SBA published an interim final rule to implement the 2016 Act (81 FR 33123) and, with the ''zero cost'' requirement satisfied for fiscal year 2016, SBA began accepting applications for assistance under the Debt Refinancing Program on June 25, 2016, the effective date of the interim final rule. With the ''zero cost'' requirement satisfied for fiscal years 2017 and 2018, the Debt Refinancing Program has continued to be in effect without interruption. The regulations governing this program are found at 13 CFR 120.882(g).

II. Summary of Comments Received

SBA received 49 comments during the comment period for the interim final rule, which closed on July 25, 2016. Of the comments received, 44, or 90%, were from Certified Development Companies, one was from a trade association, one was from a law firm, one was from a commercial real estate broker, one was from a financial institution, and one was from a private citizen. Below is a summary of the comments received.

A. Definition of Qualified Debt—Section 120.882(g)(15)

The Jobs Act authorizes the refinancing of ''Qualified Debt'' which is defined to mean, among other factors, ''indebtedness'' that ''was incurred not less than 2 years before the date of the application for assistance'', that ''is a commercial loan'', and the proceeds of which were used to acquire an Eligible Fixed Asset. *See* section 502(7)(C)(III)(aa)(AA), (BB), and (DD) of the SBIAct. In imposing the two-year requirement, Congress clearly did not want the Debt Refinancing Program to apply to new loans (*i.e.,* loans less than two years old). In implementing this statutory requirement, the current regulations define ''Qualified debt'', in part, as a ''commercial loan . . . [t]hat was incurred not less than 2 years before the date of the application for the refinancing available under [the 504 Debt Refinancing Program]''. *See* 13 CFR 120.882(g)(15) (definition of ''Qualified debt''). Debt that was refinanced through the execution of a new Note within the two year period would not be considered Qualified debt under the current regulations.

Twenty-nine commenters requested that the definition of Qualified debt be revised to include debt that has been refinanced within the 2 years prior to the date of the 504 Debt Refinancing application. The commenters argue that, as long as the debt being refinanced was originally incurred more than 2 years before application, it falls under the statutory definition. Some of the commenters also contend that the term ''indebtedness'' is broader than the term ''commercial loan'', and that SBA should look to the date of the ''original'' indebtedness and not the date that the loan was refinanced. One commenter suggested that a refinancing within two years of the application date that extends the date of the balloon payment should be allowed if the borrower did not receive any additional funds with the new loan.

SBA has reconsidered this issue and agrees that it is appropriate to consider the substance of the refinancing, rather than the form (*i.e.,* whether the most recent debt is evidenced by a new Note), to determine whether it is the same ''indebtedness'' as the prior loan. SBA has concluded that certain loans that are refinanced within two years of the date of application (the resulting loan herein referred to as the ''most recent loan'') may qualify as the same indebtedness, but only if the most recent loan is, in effect, a replacement for the prior loan. Specifically, in order to be considered the same indebtedness, the most recent loan cannot have advanced any additional funds to the Borrower (other than to pay the closing costs of the refinancing). SBA is revising the definition of ''Qualified debt'' to reflect that SBA will consider the most recent loan to be the same indebtedness as the prior loan if the effect of the most recent loan was to extend the prior loan's maturity date without advancing any additional proceeds to the Borrower. The collateral for the most recent loan must also include, at a minimum, the same Eligible Fixed Asset(s) that served as collateral for the prior loan that was refinanced. (Other terms of the most recent loan, however, such as interest rate or amortization schedule, may be different and may also include the addition of other eligible collateral.) In order to ensure that the Debt Refinancing Program complies with the statutory prohibition against refinancing new indebtedness, CDCs must submit to SBA as part of the application copies of the most recent loan and lien instruments, as well as copies of the loan and lien instruments for the loan that was replaced by the most recent loan, to show that the effect of the most recent loan was to extend the prior loan's maturity date without advancing any additional funds to the Borrower (other than to pay the closing costs of the refinancing).

In addition, SBA received comments relating to the statutory requirement that the applicant be current on all payments due for not less than one year preceding the date of application. *See* section 502(7)(C)(III)(bb) of the SBIAct. The current regulations define ''current on all payments due'' to mean that ''no payment was more than 30 days past due from either the original payment terms or modified payment terms (including deferments) if such modification was agreed to in writing by the Borrower and the lender of the existing debt no less than one year preceding the date of application.'' See 13 CFR 120.882(g)(15) (definition of ''Qualified debt'', ¶ (vii)). In the Interim Final Rule published on May 25, 2016, SBA explained that it established the requirement that the modification be executed no less than one year preceding the 504 application because a debt should not be considered ''current on all payments due for not less than one year preceding the date of application'' if the payment terms were modified during the one year period. This requirement was imposed, in part, to ensure that the Debt Refinancing Program would not be used to refinance loans that had been modified for the sole purpose of avoiding a delinquency or default within the prior year.

Some commenters requested that SBA allow a modification (including through a renewal or extension) within the one year period when the purpose of the modification is to extend a balloon payment. SBA has reconsidered this issue and agrees that modifications that extend the maturity date of the loan may be allowed, provided that, during the one year period prior to the date of application (*i.e.,* in the months prior to and after the modification), the applicant is current on all payments due, there have been no deferments of any payments, and no additional proceeds were advanced through the modification. To conform the current regulation to this revision, SBA is removing the reference to deferments from the regulatory text.

In addition, as SBA is now allowing certain refinanced loans to satisfy the 2-year indebtedness requirement described in ¶ II.A. above, these refinanced loans should not be excluded from the definition of ''current on all payments due for not less than one year preceding the date of application'' merely because the refinance occurred within the year prior to application. Thus, SBA will allow a refinanced loan to satisfy the ''current on all payments due'' requirement provided that it satisfies the same requirements as a modified loan, including that, during the one year period prior to the date of application (*i.e.,* in the months prior to and after the refinancing), the applicant was current on all payments due, there were no deferments of any payments, and no additional proceeds were advanced through the refinancing (other than to pay the closing costs of the refinancing). (To be consistent with the change to the ''Qualified debt'' definition regarding when the indebtedness is incurred, the modified or refinanced loan may also change the interest rate and other terms.)

SBA emphasizes that it expressly reserves the right to determine, at its discretion on a loan-by-loan basis, whether the modified or refinanced repayment terms fail to satisfy prudent lending standards.

B. Refinancing Projects Involving Limited or Single Purpose Properties—13 CFR 120.882(g)(5)

Concerns were expressed by 24 commenters about requiring Borrowers to contribute 15%, instead of 10%, for the refinancing of projects involving limited/single purpose properties. The commenters noted that, under the temporary Debt Refinancing Program, SBA required such Borrowers to make only a 10% contribution but, when SBA began to process applications under the reauthorized Debt Refinancing Program, SBA required Borrowers to contribute 15%. SBA notes that the temporary Debt Refinancing Program was implemented during very different economic conditions, when the projects to be refinanced under this program were sometimes significantly under-collateralized. By requiring Borrowers to contribute only 10% and not 15% for refinancing projects involving limited or single purpose properties, SBA made the program more available to Borrowers at a time when it was difficult for small businesses to access capital. Because the project was for the refinancing of an existing debt, and was not for the acquisition, construction, conversion, or expansion of a limited or single purpose property, SBA concluded that the 15% contribution was not required under statutory or regulatory requirements. *See* section 502(3)(C)(ii) and 13 CFR 120.910(a)(2). Due to the critical need to provide small businesses with access to capital during that time, SBA was willing to absorb the additional risk posed by debt refinancing projects where the

underlying collateral was limited or single purpose properties.

However, when SBA implemented the 2016 Act, SBA reconsidered this policy in light of the fact that, with the economic recovery, project properties are now typically over-collateralized and can readily provide the additional 5% equity and often more, thereby mitigating the risk presented to SBA by projects involving single or limited purpose properties in the event of liquidation. The 2016 Act states that the Debt Refinancing Program may provide ''not more than 90% of the value of the collateral'' for the refinancing of the Qualified Debt, and SBA has determined that, where the underlying collateral is limited or single purpose properties, the financing provided through the Debt Refinancing Program will be limited to 85% of the collateral value, with 15% being contributed by the Borrower.

In the event that general market conditions result again in 504 Projects that are significantly under-collateralized, however, SBA wants the Debt Refinancing Program to have the flexibility to allow Borrowers to contribute only 10% toward the cost of a project involving single or limited use properties. Accordingly, the rule will provide that, if the Refinancing Project involves a limited or single purpose building or structure, the Borrower must contribute not less than 15%; *provided, however,* that SBA may determine, in its discretion, that in the event of an economic recession, as determined by the National Bureau of Economic Research or its equivalent, the required Borrower contribution may be not less than 10% for such projects. In such circumstance, SBA will publish a notice in the **Federal Register** of its determination and setting forth the justification for the lower required Borrower contribution. This lower Borrower contribution requirement would be in effect until the first day of the calendar quarter after the economic recession has ended as determined by the National Bureau of Economic Research or its equivalent. SBA will publish a notice in the **Federal Register** to announce that the lower required Borrower contribution ceased being in effect as of that date.

With respect to the loan provided by the Third Party Lender, the statute requires the Third Party Lender to contribute 50% to the project cost when the project is financing the construction (or acquisition, conversion or expansion) of a single or limited purpose property. *See* section 502(3)(B)(ii) of the SBIAct. While this statutory requirement does not strictly apply to the refinancing of existing debt involving single/limited purpose property, SBA has considered whether Third Party Lenders should nevertheless be required to contribute 50% in the case of refinancing a debt involving such properties. As Borrowers are now often able in the current market to contribute 20% or more equity to the Refinancing Project's costs, the 504 loan would amount to 30% or less of the project cost if the Third Party Lender were required to contribute 50%, which does not maximize the economic benefit of the 504 Loan Program to the small business. Thus, SBA has determined that Third Party Lenders will not be required to contribute 50% but, as required for all projects financed under the Debt Refinancing Program, their participation must be at least equal to the SBA 504 loan.

C. Extension of Disbursement Deadline—13 CFR 120.882(g)(12)

The current rule requires that the 504 loan proceeds be disbursed within 6 months after loan approval, and authorizes the Director, Office of Financial Assistance, or his or her designee, to approve any request for extension of the disbursement period for good cause. 13 CFR 120.882(g)(12). A commenter stated that, now that the program is permanent, the rule should be revised to allow up to one year for disbursement. The commenter observed that six months may not be sufficient time to, for example, satisfy certain environmental requirements. SBA has considered this comment and agrees to change the disbursement period to nine months, and to provide the Director, Office of Financial Assistance (D/FA), or his or her designee, with the authority to approve any request for extension of the disbursement period for not more than an additional six months for good cause. SBA finds that this increase, along with the limited authority to approve any request for extension for good cause, is sufficient to address the commenter's concerns. SBA is revising 13 CFR 120.882(g)(12) accordingly.

D. Financing of Eligible Business Expenses—13 CFR 120.882(g)(6)(i) and (ii)

1. Loan-to-Value Limitations With Financing of Eligible Business Expenses

Under the Debt Refinancing Program, Borrowers may finance Eligible Business Expenses as part of the Refinancing Project if the amount of cash funds that will be provided for the Refinancing Project exceeds the amount to be paid to the lender of the Qualified debt. See 13 CFR 120.882(g)(6)(ii).

When SBA first implemented the reauthorized Debt Refinancing Program in 2016, SBA applied a maximum 75% loan-to-value (LTV) for any project that financed business expenses and limited such financing of business expenses to no more than 25% of the value of the Eligible Fixed Asset(s) securing the Qualified Debt. *See* Policy Notice 5000–1382, effective May 26, 2016. Thirty-six commenters expressed concerns that the 75% LTV was severely restrictive and would impair utilization of the program, and many urged SBA to allow for a 90% LTV for all Refinancing Projects. SBA considered these comments and decided to revise 13 CFR 120.882(g)(6)(i) to allow a maximum LTV of 85% for any project that includes the financing of Eligible Business Expenses. SBA concludes that this higher LTV will provide increased access to credit without adding undue risk to SBA.

In addition, most of the commenters expressed support for the 25% limitation on the amount that may be financed for business expenses, though SBA did receive at least one comment suggesting that the small business should determine the percentage of these expenses that may be financed. SBA notes that the financing of business expenses during Fiscal Year 2017 averaged less than 15% of the value of the Eligible Fixed Asset(s) securing the Qualified Debt. In addition, with the statutory requirement that SBA maintain the Debt Refinancing Program at zero subsidy in order for the program to be in effect during any fiscal year, SBA must be diligent in placing prudent controls on the program to mitigate SBA's risk and exposure. Accordingly, SBA has decided to limit the portion of the financing that may be for business expenses to 20% of the value of the Eligible Fixed Asset(s). In addition, if the Refinancing Project includes the financing of Eligible Business Expenses, SBA will not accept as collateral any fixed assets other than the Eligible Fixed Asset(s) securing the Qualified Debt. Accordingly, SBA is revising 13 CFR 120.882(g)(6)(i) and (ii) and the definition of ''Refinancing Project'' in 13 CFR 120.882(g)(15).

2. Eligible Business Expenses May Include Non-Capital Expenditures

Twenty-eight commenters requested that SBA allow Borrowers to finance minor renovations or ''non-substantial modifications or improvements to the Eligible Fixed Assets'' as an Eligible Business Expense under the Debt Refinancing Program. Enacted by Congress in 2010, the Jobs Act created the temporary Debt Refinancing Program for projects that do *not* involve

the expansion of a small business. *See* section 502(7)(C)(ii) of the SBIAct. SBA has concluded that the regulations would benefit from greater clarity regarding the type of minor renovations or ''non-substantial modifications or improvements'' that SBA regards as not involving the expansion of the small business.

SBA believes that a reasonable approach to this issue is to permit the financing of business expenses in the program as long as the expenses may be deducted as ordinary and necessary expenses on the small business's federal tax returns during the taxable year in which they were paid or incurred. *See* Internal Revenue Code, section 162. Examples of such expenses may include repairs, maintenance and minor improvements or renovations. Capital expenditures, on the other hand, would not be eligible for financing in the program because they have a useful life substantially beyond the taxable year. *See* Internal Revenue Code, section 263(a). Examples of such capital expenses may include the acquisition of land or improvements or betterments made to increase the value of any property. SBA believes that using this distinction between operating and capital expenditures is consistent with the statutory requirement that the Debt Refinancing Program be used for Refinancing Projects that do not involve the expansion of a small business.

Accordingly, SBA is revising the definition of Eligible Business Expenses to allow the financing of ''any other expenses of the business that are not capital expenditures.'' With the addition of this category, SBA is clarifying that the Borrower may finance any operating expense that it records and deducts as an expense in the taxable year in which it was paid or incurred, but may not finance any capital expense that is used to acquire or improve assets and which the Borrower may not claim as a deduction in the taxable year in which the expense was paid or incurred. SBA will rely upon the CDC and the small business to represent the nature of the expense and that the expense may be deducted as an ordinary and necessary expense during the taxable year in which it was paid or incurred. CDCs must document their determination regarding the nature of the expense in the credit memorandum.

SBA is also removing the phrase ''or other obligations of the business'' from the definition to clarify that, except as described below, other debt of the business is not included as an Eligible Business Expense. As SBA recently clarified, credit card debt may be included as an Eligible Business Expense if the credit card is issued in the name of the Applicant small business and the Applicant certifies that the credit card debt being refinanced was incurred exclusively for business related purposes. *See* SOP 50 10 5(J), Subpart C, Chapter 2, ¶ IV.E.3.g). SBA has also determined that business lines of credit may be included as an Eligible Business Expense if the business line of credit satisfies the same requirements as credit card debt. For debt that was incurred with a credit card or a business line of credit, the proceeds of the debt being refinanced, like all other business expenses financed under the Debt Refinancing Program, must have been used for expenses of the business that are not capital expenditures.

E. Waiver of the 50% Limitation—13 CFR 120.882(g)(10)

The 2016 Act requires that a CDC limit its financings under the 504 Loan Program so that, during any fiscal year, new financings under the Debt Refinancing Program do not exceed 50% of the dollars the CDC loaned under the 504 Loan Program during the previous fiscal year. The 2016 Act also provides that this limitation may be waived upon application by a CDC and upon SBA's determination that the refinance loan is needed for good cause. In the interim final rule, SBA stated that it would provide guidance regarding the good cause determination in its Standard Operating Procedures or other guidance documents. SBA received many comments suggesting various factors for SBA to consider in making the good cause determination, including projects that (i) assist manufacturing firms, (ii) will employ 1 full time equivalent job for every $100,000 in requested assistance, (iii) include the participation of another economic development entity, (iv) involve a borrower who has a pre-existing relationship with the CDC, or (v) involve a CDC with less than $5 million in 504 loans during the prior fiscal year. Some commenters also expressed concerns that the 50% limitation is disadvantageous to smaller or rural CDCs that may not have the same capacity as larger CDCs to finance these projects.

SBA considered these comments and concludes that the focus of the good cause determination should be only on the Borrower's financing needs, and not on the circumstances of the CDCs or other factors. Accordingly, as reflected in the recently issued SOP 50 10 5(J), Subpart C, Chapter 2, § IV.E.2, SBA will consider the following factors in determining whether there is good cause for the Borrower to obtain the refinancing through a CDC that exceeds the 50% requirement: (1) Whether the Borrower has access to other sources of financing, including other CDCs that have not exceeded their 50% cap; and (2) whether the CDC has an existing 504 loan with the Borrower that is in current status. No change to the regulation is necessary.

F. Statutory Requirements

Several commenters requested changes to other program requirements in the Debt Refinancing Program, including that SBA: (i) Allow 504 or 7(a) loans to be refinanced in the Debt Refinancing Program, (ii) allow CDCs participating in the Premier Certified Lenders Program (PCLP) to use their delegated authority to approve loans made in the Debt Refinancing Program, and (iii) reinstate the alternative job retention goal provided in the Jobs Act for Borrowers that do not meet the job creation and retention goals under sections 501(d) and (e) of the Small Business Investment SBIAct.

However, each of these program requirements is mandated by statute: the prohibition against refinancing a loan subject to a guarantee by a Federal agency is mandated by section 502(7)(C)(i)(III)(aa)(CC) of the SBIAct; the prohibition against PCLP CDCs using their delegated authority to approve loans made in the Debt Refinancing Program is mandated by section 502(7)(C)(v) of the SBIAct; and the elimination of the alternative job retention goal was made by section 521(a)(1) of the 2016 Act. SBA notes that, with the elimination of the alternate job retention goal, all applicants for a loan under the Debt Refinancing Program are required to meet the job creation and retention goals under section 501(d) and (e) of the SBIAct. Based on these goals, a 504 Project, including a project financed under the Debt Refinancing Program, must achieve one of the economic development objectives set forth in 13 CFR 120.861 or 120.862.

Accordingly, SBA cannot adopt the requested changes.

III. Section-by-Section Analysis

Except as set forth below, 13 CFR 120.882(g) remains unchanged.

Section 120.882(g) Introductory Text. In the Interim Final Rule, SBA revised the introductory text in this section to remove the following phrase that is no longer applicable: ''For applications received on or after February 17, 2011 and approved by SBA no later than September 27, 2012''. Also, with the permanent reauthorization of the Debt Refinancing Program by the 2016 Act, a specific application period is

unnecessary. No comments were received on this provision and no further changes are being made.

Section 120.882(g)(3). In the Interim Final Rule, SBA revised this section by removing the maturity date requirement. In its place, SBA inserted the 2016 Act's requirement that, for the Debt Refinancing Program to be in effect during any fiscal year, the cost to the Federal government of making guarantees under the Debt Refinancing Program and under the 504 Loan Program must be zero. No comments were received on this provision and no further changes are being made.

Section 120.882(g)(5). This paragraph is being revised to provide that, if the Refinancing Project involves a limited or single purpose building or structure, the Borrower must contribute not less than 15%. However, SBA may determine, in its discretion, that in the event of an economic recession as determined by the National Bureau of Economic Research or its equivalent, the required Borrower contribution may be not less than 10% for such projects. This lower Borrower contribution requirement may be in effect until the recession ends as determined by the National Bureau of Economic Research or its equivalent. As explained above, SBA will publish a notice in the **Federal Register** to announce the lower Borrower contribution requirement and explaining its justification, and a notice to announce that, due to the end of the recession, the lower Borrower contribution requirement is no longer in effect.

Section 120.882(g)(6). As discussed above, SBA is revising § 120.882(g)(6)(i) to allow a maximum LTV of 85% for any project that includes the financing of Eligible Business Expenses, and to limit the portion of the financing that may be used for Eligible Business Expenses to 20% of the value of the Eligible Fixed Asset(s). SBA is also revising § 120.882(g)(6)(ii) to amend the definition of Eligible Business Expenses to include ''any other expenses of the business that are not capital expenditures'', and to remove the phrase ''other obligations of the business'' from the definition to clarify that Eligible Business Expense may include credit card debt and business lines of credit in the name of the small business that were incurred exclusively for business related purposes, but no other debt of the business may be included.

Section 120.882(g)(10). As discussed above, the 2016 Act eliminated the alternate job retention goal and, accordingly, SBA removed the alternate job retention goal provision from the regulations in the Interim Final Rule.

Instead, the Interim Final Rule revised § 120.882(g)(10) to reflect the 2016 Act's requirement that a CDC limit its financings under the Debt Refinancing Program so that, during any fiscal year (October 1 to September 30), new financings under the Debt Refinancing Program do not exceed 50% of the dollars loaned by the CDC under the 504 Loan Program during the previous fiscal year. Because the 2016 Act provides that the 50% limitation applies to the dollars loaned under the 504 Loan Program during the previous fiscal year, all financings made by the CDC during the previous fiscal year will be included in determining this number, including those financings made under the Debt Refinancing Program.

The Interim Final Rule provided that, as authorized by the 2016 Act, the 50% limitation may be waived upon application by a CDC and a determination by SBA that the refinance loan is needed for good cause. As discussed above, SBA received comments on this provision and SBA has issued waiver guidance in the recently issued Standard Operating Procedure 50 10 5(J). SBA will monitor the implementation of this guidance and update it as needed in its policy guidance. For clarity, SBA is changing the term ''refinance loan'' to ''504 loan'' in the last sentence of section 120.882(g)((10). No further changes are being made to the regulation.

Section 120.882(g)(12). As discussed above, this paragraph is being revised to change the period by which a loan must be disbursed from six months to nine months. The Director, Office of Financial Assistance (D/FA), or his or her designee, will have the authority to approve any request for extension of the disbursement period for not more than an additional six months for good cause.

Section 120.882(g)(13). This section prohibits the Third Party Loan from being sold on the secondary market as a part of a pool guaranteed under subpart J of part 120 when the debt being refinanced is same institution debt. Subpart J of part 120, the Secondary Market Guarantee Program for First Lien Position 504 Loan Pools, expired on September 23, 2012; however, should this program be reauthorized, SBA wants to ensure that this prohibition remains in effect. Accordingly, in the Interim Final Rule, SBA revised this provision to make it clear that the prohibition would apply to any successor to the program described in subpart J of part 120. No comments were received on this provision and no further changes are being made.

Section 120.882(g)(15) (Definition of ''Qualified debt''). As discussed above, SBA is revising the criterion in paragraph (i) to allow certain loans that are refinanced within the two years prior to the date of application to be eligible as the same ''indebtedness'' if the effect of the refinancing was to extend the maturity date without advancing any additional proceeds, and the collateral for the most recent loan includes, at a minimum, the same Eligible Fixed Asset(s) that served as collateral for the former loan that was refinanced. Other terms of the most recent loan, such as interest rate and the addition of other collateral, may be different. To be considered for eligibility by SBA, the loan documents and lien instruments for the most recent loan, as well as the loan documents and lien instruments for the loan that was replaced by the most recent loan, must be submitted to SBA as part of the application.

SBA is also revising the definition of ''current on all payments due'' in paragraph (vii) to allow the payment terms of a loan to be modified less than one year prior to the date of application (whether through a modification to an existing Note or a refinancing that results in a new Note) if the purpose of the modification or refinancing is to extend the maturity date of the loan, including balloon payments, no additional proceeds were advanced to the Borrower, and the Borrower was current on all payments due for the one year period prior to the date of application (*i.e.,* in the months prior to and after the effective date of the modification or refinancing), including that there were no deferments of any payment.

SBA emphasizes that it reserves the right to determine, at its discretion on a loan-by-loan basis, whether the terms of any modification or refinancing are consistent with prudent lending standards.

Section 120.882(g)(15) (Definition of ''Refinancing Project''). SBA is revising this definition to provide that, if the Refinancing Project includes the financing of Eligible Business Expenses, SBA will not accept as collateral any fixed assets other than the Eligible Fixed Asset(s) securing the Qualified debt.

Compliance With Executive Orders 12866, 12988, 13132, and 13563, 13771, the Paperwork Reduction Act (44 U.S.C., Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget has determined that this rule does not constitute a ''significant regulatory action'' under Executive Order 12866. This rule is also not a major rule under the Congressional Review Act.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have preemptive effect or retroactive effect.

Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. It will 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 the various levels of government, as specified in the Executive Order. As such it does not warrant the preparation of a Federalism Assessment.

Executive Order 13563

The Consolidated Appropriations Act, 2016, reauthorized the Debt Refinancing Program, which was first authorized by the Jobs Act. The Agency received significant public comments on the Jobs Act interim final rule that was issued to implement the temporary Debt Refinancing Program (*see* 76 FR 9213, February 17, 2011). To assist in developing that interim final rule, the Agency held a public forum on November 17, 2010 in Boston, Massachusetts. As discussed above, SBA received a significant number of public comments on the interim final rule that was published to implement the reauthorized Debt Refinancing Program, and the revisions made by this final rule are the result of the public participation in the rulemaking process.

Executive Order 13771

This rule is not an Executive Order 13771 regulatory action because it is not significant under E.O. 12866.

Paperwork Reduction Act, 44 U.S.C., Ch. 35

SBA has determined that this final rule does not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act.

Regulatory Flexibility Act, 5 U.S.C. 601–612

The RFA requires administrative agencies to consider the effect of their actions on small entities, including small non-profit businesses, and small local governments. Pursuant to the RFA, when an agency issues a rule, the agency must prepare an analysis that describes whether the impact of the rule will have a significant economic impact on a substantial number of these small entities. However, the RFA requires such analysis only where notice and comment rulemaking is required. This rule finalizes the interim final rule that was published in 2016 to implement the reauthorized Debt Refinancing Program. In issuing that rule, SBA provided just cause why it could be published without notice and comment, and therefore, exempted from the RFA requirement to prepare an initial regulatory flexibility analysis. Since this final rule merely finalizes that exempted interim rule, SBA believes a final regulatory analysis is also not required.

List of Subjects in 13 CFR Part 120

Loan programs—business, Small businesses, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 13 CFR part 120 which was published at 81 FR 33123 on May 25, 2016, is adopted as a final rule with the following changes:

PART 120—BUSINESS LOANS

■ 1. The authority citation for 13 CFR part 120 is revised to read as follows:

Authority: 15 U.S.C. 634(b) (6), (b) (7), (b) (14), (h), and note, 636(a), (h) and (m), 650, 687(f), 696(3) and (7), and 697(a) and (e); Pub. L. 111–5, 123 Stat. 115, Pub. L. 111–240, 124 Stat. 2504.

■ 2. Amend § 120.882 by:
■ a. Adding three sentences after the first sentence of paragraph (g)(5), and removing ''10%'' in the last sentence;
■ b. Revising paragraph (g)(6)(i);
■ c. Removing the third and fourth sentences of paragraph (g)(6)(ii) and adding in their place five sentences;
■ d. Removing the words ''refinance loan'' in the last sentence of paragraph (g)(10) and adding the words ''504 loan'' in their place;
■ e. Revising paragraph (g)(12);
■ f. Removing the semicolon at the end of paragraph (i) in the definition of ''Qualified debt'' in paragraph (g)(15), adding a period in its place, and adding two sentences to the end of the paragraph;
■ g. Removing the second sentence of paragraph (vii) in the definition of ''Qualified debt'' in paragraph (g)(15) and adding in its place two sentences; and
■ h. Revising the definition of ''Refinancing Project'' in paragraph (g)(15).

The additions and revisions read as follows:

§ 120.882 Eligible Project costs for 504 loans.

* * * * *

* * *

(g) * * *

(5) * * * If the Refinancing Project involves a limited or single purpose building or structure, the Borrower must contribute not less than 15% (excluding administrative costs), unless SBA determines, in its discretion, and publishes a notice in the **Federal Register**, that due to an economic recession, as determined by the National Bureau of Economic Research or its equivalent, Borrowers may contribute not less than 10% for Refinancing Projects involving a limited or single purpose property during the recession. The lower required contribution by the Borrower will be in effect until the first day of the calendar quarter following the end of the economic recession as determined by the National Bureau of Economic Research or its equivalent. SBA will publish a notice in the **Federal Register** announcing the date on which the requirement of the lower Borrower contribution ended. * * *

(6)(i) The portion of the Refinancing Project provided by the 504 loan and the Third Party Loan may be no more than 90% of the fair market value of the fixed assets that will serve as collateral, except that if the Borrower's application includes a request to finance the Eligible Business Expenses described in paragraph (g)(6)(ii) of this section, the portion of the Refinancing Project provided by the 504 loan and the Third Party Loan may be no more than 85% of the fair market value of the fixed assets that will serve as collateral and the Borrower may receive no more than 20% of the fair market value of the Eligible Fixed Asset(s) securing the Qualified Debt for Eligible Business Expenses;

(ii) * * * For the purposes of this paragraph (g), ''Eligible Business Expenses'' are limited to the operating expenses of the business that were incurred but not paid prior to the date of application or that will become due for payment within 18 months after the date of application. These expenses may include salaries, rent, utilities, inventory, and other expenses of the business that are not capital expenditures. Debt is not included as an

Eligible Business Expense, except debt that was incurred with a credit card or a business line of credit may be included if the credit card or business line of credit is issued in the name of the small business and the Applicant certifies that the debt being refinanced was incurred exclusively for business related purposes. Loan proceeds must not be used to refinance any personal expenses. Both the CDC and the Borrower must certify in the application that the funds will be used to cover Eligible Business Expenses. * * *

* * * * *

(12) The 504 loans approved under this paragraph (g) must be disbursed within 9 months after loan approval. The Director, Office of Financial Assistance, or his or her designee, may approve a request for extension of the disbursement period for an additional 6 months for good cause.

* * * * *

(15) * * *

Qualified debt is a commercial loan:

* * *

(i) * * * A commercial loan that was refinanced within the two years prior to the date of application (the most recent loan) may be deemed incurred not less than 2 years before the date of the application provided that the effect of the most recent loan was to extend the maturity date without advancing any additional proceeds (except to cover closing costs) and the collateral for the most recent loan includes, at a minimum, the same Eligible Fixed Asset(s) that served as collateral for the former loan that was refinanced. The loan documents and lien instruments for the most recent loan, as well as the loan documents and lien instruments for the loan that was replaced by the most recent loan, must be submitted to SBA as part of the application.

* * * * *

(vii) * * * For the purposes of this paragraph (vii), ''current on all payments due'' means that no payment was more than 30 days past due from either the original payment terms or modified payment terms (whether through a modification to an existing Note or through a refinancing that results in a new Note). The modification (or refinancing) must have been agreed to in writing by the Borrower and the lender of the existing debt no less than one year preceding the date of application, except that a modified (or refinanced) loan may be allowed if the purpose of the modification (or refinancing) was to extend the maturity date of the loan, including any balloon payment, and if, during the one year period prior to the date of application (*i.e.,* in the months prior to and after the modification or refinancing), the Borrower was current on all payments due, there have been no deferments of any payments, and no additional proceeds were advanced through the modification or refinancing (except to cover closing costs). * * *

* * * * *

Refinancing Project means the fair market value of the Eligible Fixed Asset(s) securing the qualified debt and any other fixed assets acceptable to SBA, except that if the Refinancing Project includes the financing of Eligible Business Expenses, SBA will not accept as collateral any fixed assets other than the Eligible Fixed Asset(s) securing the Qualified Debt.

* * * * *

Dated: April 26, 2018.

Linda E. McMahon,

Administrator.

[FR Doc. 2018–09638 Filed 5–4–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

Express Bridge Loan Pilot Program; Modification of Fee Policy

AGENCY: U.S. Small Business Administration.

ACTION: Notification of change to Express Bridge Loan Pilot Program and impact on regulatory provision.

SUMMARY: On October 16, 2017, the U.S. Small Business Administration (SBA) published a document announcing the Express Bridge Loan Pilot Program (Express Bridge Pilot). In that document, SBA provided an overview of the Express Bridge Pilot and modified an Agency regulation relating to loan underwriting for loans made under the Express Bridge Pilot. SBA continues to refine and improve the design of the Express Bridge Pilot and is issuing this document to revise the program requirements, including the modification of an Agency regulation relating to fees that can be collected from the Applicant or Borrower in connection with a loan made under the Express Bridge Pilot.

DATES: The revised program requirements described in this document apply to all Express Bridge Pilot loans approved on or after May 7, 2018, and the Express Bridge Pilot will remain available through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Dianna Seaborn, Director, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416; Telephone (202) 205–3645; email address: *dianna.seaborn@sba.gov.*

SUPPLEMENTARY INFORMATION: On October 16, 2017, SBA published a document announcing the Express Bridge Pilot. (82 FR 47958) The Express Bridge Pilot is designed to supplement the Agency's disaster response capabilities and authorizes the Agency's 7(a) Lenders with SBA Express lending authority to deliver expedited SBA-guaranteed financing on an emergency basis for disaster-related purposes to small businesses located in communities impacted by a Presidentially-declared disaster, while the businesses apply for and await long-term financing (including through SBA's direct disaster loan program, if eligible).

The Express Bridge Pilot applies the policies and procedures in place for the Agency's SBA Express program, except as outlined in the **Federal Register** document published on October 16, 2017. Pursuant to the authority provided to SBA under 13 CFR 120.3 to suspend, modify or waive certain regulations in establishing and testing pilot loan initiatives, SBA modified the regulation at 13 CFR 120.150 (''What are SBA's lending criteria?''), which applies to loans made in the 7(a) Business Loan Program. SBA modified the regulation in order to minimize the burdens on the businesses applying for loans through the Express Bridge Pilot and to expand the opportunities for SBA Express lenders to participate in the pilot.

SBA continues to refine and improve the design of the Express Bridge Pilot and, therefore, is issuing this document to clarify the fees that Lenders or third parties are able to collect from Applicants or Borrowers in connection with loans made under the pilot. All Express Bridge Pilot loans are subject to the same upfront guaranty fees required for 7(a) loans of similar size and maturity as set forth in 13 CFR 120.220. In addition, all Express Bridge Pilot loans are subject to the same Lender's annual service fee required for all 7(a) loans as set forth in 13 CFR 120.220(f).

In order to ensure that Applicants and Borrowers are charged only those additional fees reasonably necessary in connection with an Express Bridge Pilot loan, SBA is modifying the regulation at 13 CFR 120.221 (''Fees and expenses which the Lender may collect from a loan applicant or Borrower''), using the term modify as contemplated under 13 CFR 120.3, to permit Lenders to collect only the following:

1. *Lender Fees:* An SBA Express Lender must not impose any fees or direct costs on an Express Bridge Pilot Applicant or Borrower, except for the following:

a. *Application Fee:* SBA Express Lenders may charge an Express Bridge Pilot Applicant an application fee. The maximum permissible application fee is 2% of the loan amount or $250, whichever is greater. If an application fee is charged, it must be disclosed on SBA Form 159(7a), Fee Disclosure Form and Compensation Agreement for Agent Services in Connection with a SBA 7(a) Loan. If an undisbursed loan is canceled, the Lender may retain the application fee;

b. *Late Payment Fee:* A late payment fee not to exceed 5 percent of the scheduled Express Bridge Pilot loan payment; and

c. *Liquidation Costs:* The reasonable direct costs of liquidation.

2. *Prohibition on all other fees and charges, including by loan packagers, referral agents or brokers.* Except as permitted in 1. above, no other fee or costs may be charged to an Express Bridge Pilot Applicant or Borrower by the Lender. In addition, no fee or costs may be charged to an Express Bridge Pilot Applicant or Borrower by any third party in connection with an Express Bridge Pilot loan, including any referral fee, broker's fee, or similar fee.

The modification of this regulation will permit SBA Express lenders to recoup some of their costs in processing the application, without subjecting the Applicant to excessive or unnecessary fees for these small guaranteed loans that are intended to provide immediate cash to assist the small business with rebuilding and continuing or restarting its operations while awaiting long-term disaster financing. SBA believes that the costs of the program should be kept as low as possible to aid the disaster-affected small business. The application fee is optional; therefore an SBA Express Lender may choose not to collect an application fee from an Express Bridge Pilot Applicant. Additionally, because an Express Bridge Pilot loan Applicant must have had an existing banking relationship with the SBA Express lender, there is no need for either the Applicant or the Lender to pay a referral fee, broker's fee, or similar fee for these loans.

SBA's modification of 13 CFR 120.221 is authorized by 13 CFR 120.3 of its regulations, which provides that the SBA Administrator may suspend, modify or waive rules for a limited period of time to test new programs or ideas. This modification applies only to loans made under the Express Bridge Pilot and will last only for the duration of the pilot, which expires September 30, 2020. As part of the Express Bridge Pilot, this modification applies only to those small businesses that were located, as of the date of the applicable disaster, in counties that have been Presidentially-declared as disaster areas, plus any contiguous counties. A listing of Presidentially-declared disaster declarations, including primary and contiguous counties can be located at *www.sba.gov/disaster.*

All other SBA terms and conditions and regulatory waivers related to the Express Bridge Pilot remain unchanged.

SBA will provide more detailed guidance in the form of a program guide, which will be available on SBA's website, *http://www.sba.gov.* SBA may also provide additional guidance, if needed, through SBA notices, which also will be published on SBA's website, *http://www.sba.gov.*

Authority: 15 U.S.C. 636(a)(25); 13 CFR 120.3.

Dated: April 26, 2018.

Linda E. McMahon,

Administrator.

[FR Doc. 2018–09627 Filed 5–4–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1163; Product Identifier 2017–CE–041–AD; Amendment 39–19260; AD 2018–09–04]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace Corporation Models G–IV and GIV–X airplanes. This AD was prompted by the potential for fatigue cracks developing in the main landing gear actuator attachment fitting that had a certain repair incorporated. This AD requires incorporating new revisions into the Instructions for Continued Airworthiness of the Limitations section of the FAA-approved maintenance program (*e.g.,* maintenance manual) that establish an inspection cycle for the repaired MLG side brace actuator fittings. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 11, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 11, 2018.

ADDRESSES: For service information identified in this final rule, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Savannah, Georgia 31402–2206; telephone: (800) 810–4853; fax 912–965–3520; email: *pubs@gulfstream.com;* internet: *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1163.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1163; 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 final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: William O. Herderich, Aerospace Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5547; fax: (404) 474–5605; email: *william.o.herderich@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Gulfstream Aerospace Corporation Models G–IV and GIV–X airplanes. The NPRM published in the **Federal Register** on December 12, 2017 (82 FR 58362). The NPRM was prompted by the potential for fatigue cracks developing in the main landing gear actuator attachment fitting that had a certain repair incorporated. The NPRM proposed to require incorporating new revisions into the

Instructions for Continued Airworthiness of the Limitations section of the FAA-approved maintenance program (*e.g.,* maintenance manual) that establish an inspection cycle for the repaired MLG side brace actuator fittings. We are issuing this AD to address the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Change Compliance Time

Gulfstream Aerospace Corporation stated that the compliance time for the actions required in the proposed AD should be changed to be in-line with the service information incorporated by reference in the proposed AD.

Gulfstream Aerospace Corporation stated that the compliance time specified in the service information incorporated by reference in the proposed AD is 24 months from September 16, 2016. Gulfstream Aerospace Corporation believes that the 100-hour time-in-service (TIS) compliance time after the effective date of the proposed AD significantly reduces the original compliance time and may cause an undue burden on the owner/operators of the affected airplanes.

We agree that the compliance time can be changed to more fully coincide with the service bulletin without affecting the safety risk of this AD. We have changed the compliance time of this AD to ''Within the next 100 hours time-in-service (TIS) after the effective date of this AD or within the next 3 months after the effective date of this AD, whichever occurs later.'' The 3-month compliance time combined with the 35 days after publication in the **Federal Register** effective date should coincide with the compliance time in the service bulletin.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Gulfstream G350 Customer Bulletin Number 192A, dated June 15, 2017, including Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016 (for model Gulfstream G350); Gulfstream G450 Customer Bulletin 192A, dated June 15, 2017, including Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016 (for model Gulfstream G450); Gulfstream IV Customer Bulletin Number 238A, dated June 15, 2017, including Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016 (for model Gulfstream IV); Gulfstream G300 Customer Bulletin Number 238A, dated June 15, 2017, including Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016 (for model Gulfstream G300); and Gulfstream G400 Customer Bulletin Number 238A, dated June 15, 2017, including Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016 (for model Gulfstream G400). For the applicable models, the service information describes procedures for inspecting maintenance records to determine if repair SE05732102 for the main landing gear side brace fitting has been incorporated and determining initial and repetitive inspection requirements for the main landing gear side brace fitting. 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.

Costs of Compliance

We estimate that this AD affects 709 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect Maintenance Records	1 work-hour × $85 per hour = $85	Not applicable	$85	$60,265
Incorporate new revisions into the Instructions for Continued Airworthiness of the Limitations section of the FAA-approved maintenance program (*e.g.,* maintenance manual).	1 work-hour × $85 per hour = $85	Not applicable	85	60,265

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.

We are 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 aircraft 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs

applicable to small airplanes, gliders, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:

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

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2018–09–04 Gulfstream Aerospace Corporation: Amendment 39–19260; Docket No. FAA–2017–1163; Product Identifier 2017–CE–041–AD.

(a) Effective Date

This AD is effective June 11, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Gulfstream Aerospace Corporation model airplanes that are certificated in any category:

(1) Model G–IV, serial numbers (S/Ns) 1000 through 1399 having Aircraft Service Change (ASC) 416A (MSG–3) incorporated; and S/Ns 1400 through 1535; and

(2) Model GIV–X, S/Ns 4001 through 4355.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by the potential for fatigue cracks in the main landing gear (MLG) actuator attachment fitting that had a certain repair incorporated. We are issuing this AD to prevent failure of the MLG actuator attachment. The unsafe condition, if not addressed, could compromise the lateral support of the MLG during ground maneuvers, possibly leading to collapse of the affected MLG with consequent loss of control. In addition, this condition could also cause the MLG side brace to fail, which could result in a penetration of the wing fuel tank causing an uncontained fire.

(f) Compliance

At whichever of the following in paragraphs (f)(1) and (f)(2) that occurs later, comply with the actions in paragraphs (g) through (i) of this AD, unless already done.

(1) Within the next 100 hours time-in-service after June 11, 2018 (the effective date of this AD); or

(2) Within the next 3 months after June 11, 2018 (the effective date of this AD).

(g) Inspect Maintenance Records

Inspect the airplane maintenance records to determine if repair SE05732102 for the MLG side brace fitting has been incorporated. To do this inspection, use the Accomplishment Instructions in Gulfstream G350 Customer Bulletin Number 192A; Gulfstream G450 Customer Bulletin 192A; Gulfstream IV Customer Bulletin Number 238A; Gulfstream G300 Customer Bulletin Number 238A; and Gulfstream G400 Customer Bulletin Number 238A; all dated June 15, 2017, as applicable. The service information referenced in this paragraph specifies sending a service reply card back to Gulfstream Aerospace Corporation if repair SE05732102 for the MLG side brace fitting has been not been incorporated. This action is not required in this AD.

(h) Determine Initial and Repetitive Inspection Requirements

If it is determined during the maintenance records inspection required in paragraph (g) of this AD that repair SE05732102 for the MLG side brace fitting has been incorporated, determine the initial and repetitive inspection requirements using the Accomplishment Instructions of the service information identified in paragraph (g) of this AD along with the following documents, as applicable. Comply with the inspection requirements as determined.

(1) Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016, to Gulfstream G350 Customer Bulletin No. 192A, dated June 15, 2017;

(2) Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016, to Gulfstream G450 Customer Bulletin No. 192A, dated June 15, 2017;

(3) Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016, to Gulfstream IV Customer Bulletin No. 283A, dated June 15, 2017;

(4) Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016, to Gulfstream G300 Customer Bulletin No. 283A, dated June 15, 2017; and

(5) Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016, to Gulfstream G400 Customer Bulletin No. 283A, dated June 15, 2017.

(i) Revise Limitations Section

Insert the documents listed in paragraphs (h)(1) through (5) of this AD into the Instructions for Continued Airworthiness of the Limitations section of the FAA-approved maintenance program (*e.g.,* maintenance manual), as applicable. The revised limitations sections establish inspections of the repaired MLG side brace actuator fittings.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta 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 (k) 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.

(3) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (g) through (i) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

For more information about this AD, contact William O. Herderich, Aerospace Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5547; fax: (404) 474–5605; email: *william.o.herderich@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Gulfstream G350 Customer Bulletin Number 192A, dated June 15, 2017, that incorporates Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016.

(ii) Gulfstream G450 Customer Bulletin 192A, dated June 15, 2017, that incorporates Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016.

(iii) Gulfstream IV Customer Bulletin Number 238A, dated June 15, 2017, that incorporates Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016.

(iv) Gulfstream G300 Customer Bulletin Number 238A, dated June 15, 2017, that incorporates Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016.

(v) Gulfstream G400 Customer Bulletin Number 238A, dated June 15, 2017, that incorporates Appendix A, Gulfstream Document GIV–SGER–553, Revision A, Instructions for Continued Airworthiness for Gulfstream Repair Drawing SE05732102, dated December 14, 2016.

(3) For Gulfstream Aerospace Corporation service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Savannah, Georgia 31402–2206; telephone: (800) 810–4853; fax 912–965–3520; email: *pubs@gulfstream.com;* internet: *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.*

(4) You may view this service information at FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on April 19, 2018.

Melvin Johnson,

Deputy Director, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–08956 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1245; Product Identifier 2017–NM–099–AD; Amendment 39–19266; AD 2018–09–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A318 series airplanes and Model A319 series airplanes; all Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and all Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the holes of the upper cleat to upper stringer attachments at certain areas of the left- and right-hand wings are subject to widespread fatigue damage (WFD). This AD requires modifying the holes of the upper cleat to upper stringer attachments at certain areas of the left- and right-hand wings. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 11, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 11, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 44 51; email: *account.airworth-eas@airbus.com;* internet: *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1245.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1245; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A318 series airplanes and Model A319 series airplanes; all Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and all Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The NPRM published in the **Federal Register** on January 12, 2018 (83 FR 1579) (''the NPRM''). The NPRM was prompted by an evaluation by the DAH indicating that the holes of the upper cleat to upper stringer attachments at certain areas of the left- and right-hand wings are subject to WFD. The NPRM proposed to require modifying the holes of the upper cleat to upper stringer attachments at certain areas of the left- and right-hand wings. We are issuing this AD to prevent fatigue cracking in the stringer attachment holes of the wings, which could result in reduced structural integrity of the wings.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0117, dated July 7, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A318 series airplanes and Model A319 series

airplanes; all Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and all Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

> Within the scope of work of service life extension for A320 aeroplanes and of widespread fatigue damage evaluations, it has been determined that a structural modification is required to allow the aeroplanes to continue operation up to the limit of validity (LoV).
>
> This condition, if not corrected, may affect the structural integrity of the wing.
>
> To address this potential unsafe condition, Airbus issued [service bulletin] SB A320–57–1208, providing instructions to oversize the holes of the upper cleat to upper stringer attachments at Rib 2 to Rib 7 (inclusive).
>
> For the reason described above, this [EASA] AD requires modification of the affected holes.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1245.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment. United Airlines agreed with the intent of the NPRM.

Request To Clarify Applicability

Allegiant Air asked that we clarify the manufacturer serial numbers (MSNs) identified in the applicability section of the proposed AD. Allegiant Air stated that the effectivity specified in Airbus Service Bulletin A320–57–1208, dated November 21, 2016, identifies airplanes up to and including MSN 7493, and asked about airplanes having MSNs higher than 7493. Allegiant Air noted that it has 11 Model A320 airplanes with MSNs outside those listed in Airbus Service Bulletin A320–57–1208, dated November 21, 2016. Allegiant Air added that it understands the AD takes precedence over the service information, but there are several configurations listed therein. Allegiant Air also added that since the MSNs in question are not listed in the effectivity of the service information, an operator with an MSN outside the effectivity will not know which modification kit to order.

We agree to clarify. The effectivity in Airbus Service Bulletin A320–57–1208, dated November 21, 2016, does not include all MSNs for Model A320 airplanes, and the applicability specified in paragraph (c) of this AD includes all MSNs for Model A320 airplanes, except for airplanes having certain modifications. We acknowledge that the referenced service information may not be adequate for certain airplane configurations. Therefore, we have revised paragraph (g) of this AD to provide an option for doing the modification, including identification of the appropriate modification kit, using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus's EASA Design Organization Approval (DOA).

In addition, Airbus has informed us that Revision 1 of the referenced service information will expand the effectivity to include MSNs up to 8555. Airbus has also informed us that, upon request, it will issue a technical adaptation as an interim method of compliance until a revised service bulletin is issued.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Airbus has issued Airbus Service Bulletin A320–57–1208, dated November 21, 2016. This service information describes procedures for modifying the stringer attachments at rib 2 through rib 7 of the left- and right-hand wings. The modification includes oversizing the holes, doing an eddy current inspection of the affected holes for damage, and repair. 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.

Costs of Compliance

We estimate that this AD affects 1,136 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification (by oversizing and doing eddy current inspection).	125 work-hours × $85 per hour = $10,625	$26,260	$36,885	$41,901,360

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

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.

We are 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 aircraft 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:

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

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

3. Will not affect intrastate aviation in Alaska, and

4. 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2018–09–09 Airbus: Amendment 39–19266; Docket No. FAA–2017–1245; Product Identifier 2017–NM–099–AD.

(a) Effective Date

This AD is effective June 11, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category; all manufacturer serial numbers, except airplanes specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model A318 series airplanes on which Airbus Modification (Mod) 39195 has been embodied in production or Airbus Service Bulletin A320–00–1219 has been embodied in service.

(2) Model A319 series airplanes on which Airbus Mod 28238, Mod 28162, and Mod 28342 have been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by an evaluation by the design approval holder indicating that the holes of the upper cleat to upper stringer attachments at rib 2 through rib 7 of the left- and right-hand wings are subject to widespread fatigue damage. We are issuing this AD to prevent fatigue cracking in the stringer attachment holes of the wings, which could result in reduced structural integrity of the wings.

(f) Compliance

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

(g) Modification

Before reaching the upper limit, but not before reaching the lower limit, as defined in table 1 to paragraph (g) of this AD, as applicable: Modify the holes of the upper cleat to upper stringer attachments at rib 2 through rib 7 inclusive, on the left- and right-hand wings by oversizing the holes, doing eddy current inspections of the holes for damage, and repairing any damage found before further flight, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1208, dated November 21, 2016, except as required by paragraph (h) of this AD; or using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

Table 1 to paragraph (g) of this AD – *Window of Embodiment (Total Accumulated Flight Hours (TFH) or Total Accumulated Flight Cycles (TFC), whichever occurs first since airplane first flight)*

Airplanes affected		Lower Limit		Upper Limit	
		TFH	TFC	TFH	TFC
A318-100	All	94,000	47,000	159,200	79,600
A319-100 and A320-200	Pre-mod 160001 and Pre-Airbus Service Bulletin A320-57-1193	94,000	47,000	159,200	79,600
A319-100 and A320-200	Post-mod 160001 or Post-Airbus Service Bulletin A320-57-1193	52,260	26,130	101,610	50,805
A321-100 and A321-200	Pre-mod 160021	101,200	50,600	148,300	74,100

(h) Service Information Exception

Where Airbus Service Bulletin A320–57–1208, dated November 21, 2016, specifies to contact Airbus for appropriate action, and specifies that action as ''RC'' (Required for Compliance): Before further flight, accomplish corrective actions in accordance with the procedures specified in paragraph (i)(2) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (h) of this AD: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0117, dated July 7, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1245.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(k) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320–57–1208, dated November 21, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 44 51; email: *account.airworth-eas@airbus.com;* internet: *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on April 20, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–09280 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0838; Product Identifier 2017–NE–33–AD; Amendment 39–19275; AD 2018–10–01]

RIN 2120–AA64

Airworthiness Directives; Safran Helicopter Engines, S.A., Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Safran Helicopter Engines, S.A., Arriel 2E turboshaft engines. This AD was prompted by reports of ruptured front support pins on the accessory gearbox front support. This AD requires replacement of the accessory gearbox front support. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective June 11, 2018.

ADDRESSES: For service information identified in this final rule, contact Safran Helicopter Engines, S.A., 40220 Tarnos, France; phone: (33) 05 59 74 40 00; fax: (33) 05 59 74 45 15. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0838.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0838; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Robert Green, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue; phone: 781–238–7754; fax: 781–238–7199; email: *robert.green@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Safran Helicopter Engines, S.A., Arriel 2E turboshaft engines. The NPRM published in the **Federal Register** on November 3, 2017 (82 FR 51170). The NPRM was prompted by reports of ruptured front support pins on the accessory gearbox front support. The NPRM proposed to require replacement of the accessory gearbox front support. We are issuing this AD to address the unsafe condition on these products.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2016–0235, dated November 24, 2016 (referred to after this as the MCAI), to

address the unsafe condition on these products. The MCAI states:

Some cases were reported of ruptured front support pins on ARRIEL 1E2 engines. That condition, if not detected and corrected, could lead to the loss of the load path integrity of the engine front support. Consequently, Turboméca issued Mandatory Service Bulletin (MSB) 292 72 0842 to provide instructions for the inspection of the pins and front support replacement, and EASA issued AD 2015–0064 (later revised) to require those actions. Since EASA AD 2015–0064R1 was issued, SAFRAN Helicopter Engines developed a new pin design, in order to increase the mechanical strength of the pin, through modification TU380, for ARRIEL 1E2 engines. Although no cases of front support pin rupture have been reported on ARRIEL 2E engines, since the ARRIEL 1E2 and 2E type designs have the same front support, SAFRAN Helicopter Engines decided to also apply this new pin design on ARRIEL 2E engines through modification TU197. To address this potential unsafe condition, SAFRAN Helicopter Engines decided, as precautionary measure, to replace the front support on ARRIEL 2E engines, and published MSB 292 72 2197 to provide instructions for in-service front support replacement. For the reasons described above, this [EASA] AD requires modification of the affected engines by replacement of each pre-mod TU197 front support.

You may obtain further information by examining the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0838.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed.

Related Service Information

We reviewed Safran Helicopter Engines, S.A., Mandatory Service Bulletin (MSB) No. 292 72 2197, Version A, dated September 15, 2016. The MSB describes procedures for replacement of the accessory gearbox front support.

Costs of Compliance

We estimate that this AD affects 28 engines installed on aircraft of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Front support replacement	2 work-hours × $85 per hour = $170	$19,731	$19,901	$557,228

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.

We are 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 aircraft 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 AD:

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

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2018–10–01 Safran Helicopter Engines, S.A.: Amendment 39–19275; Docket No. FAA–2017–0838; Product Identifier 2017–NE–33–AD.

(a) Effective Date

This AD is effective June 11, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Safran Helicopter Engines, S.A., Arriel 2E turboshaft engines with front support, part number 0 292 11 715 0, installed (pre-mod TU 197 configuration).

(d) Subject

Joint Aircraft System Component (JASC) Code 8300, Accessory Gearboxes.

(e) Unsafe Condition

This AD was prompted by reports of ruptured front support pins on the accessory gearbox front support. We are issuing this AD to prevent failure of a front support, loss of

engine thrust control and reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

Before the accessory gearbox and transmission shaft module (Module 01) accumulates 1,600 engine operating hours since new, or within 80 engine operating hours after the effective date of this AD, whichever occurs later, replace the front support with a part eligible for installation.

(h) Definition

For the purpose of this AD, a part eligible for installation is a Module 01 with a pre-mod TU 197 front support, that has not accumulated more than 1,680 engine operating hours since new; or a Module 01 with a post-mod TU 197 front support.

(i) Installation Prohibition

As of the effective date of this AD, you may not install a pre-mod TU 197 front support on any engine with a post-mod TU 197 front support installed.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, FAA, ECO Branch, 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 ECO Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(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.

(k) Related Information

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7754; fax: 781–238–7199; email: *robert.green@faa.gov.*

(2) Refer to EASA AD 2016–0235, dated November 24, 2016, for more information. You may examine the EASA AD in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2017–0838.

(l) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on May 1, 2018.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–09466 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0721; Airspace Docket No. 17–AGL–15]

Amendment of Class E Airspace; Charlotte, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Fitch H. Beach Airport, Charlotte, MI, due to the decommissioning of the Lansing VHF omnidirectional range (VOR) and collocated tactical air navigation (TACAN) which provided navigation guidance for the instrument procedures to this airport. The Lansing VOR/TACAN is being decommissioned as part of the VOR Minimum Operational Network (MON) Program. This action enhances safety and management of instrument flight rules (IFR) operations at this airport. Additionally, the geographic coordinates of the airport are being adjusted to coincide with the FAA's aeronautical database. An editorial change is also being made removing the city associated with the airport name in the airspace legal designation.

DATES: Effective 0901 UTC, July 19, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Fitch H. Beach Airport, Charlotte, MI, to support IFR operations for instrument approach procedures at the airport.

History

The FAA published notice of proposed rulemaking (NPRM) in the **Federal Register** (82 FR 44541; September 25, 2017) for Docket No. FAA–2017–0721 to modify the Class E airspace extending upward from 700 feet above the surface at Fitch H. Beach Airport, Charlotte, MI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received stating ''. . . increasing one class of airspace would diminish the boundary between two. This would require the Pilot In Command to request access in their airspace.''

The FAA does not agree. The airspace classification, currently Class E airspace extending upward from 700 feet above the surface, is being amended to increase the radius of the airspace by 0.1 mile to fully protect the transitional IFR requirements to and from the terminal and en route environments at Fitch H. Beach Airport, Charlotte, MI, as required by FAA Order 7400.2L, Procedures for Handling Airspace Matters. This amendment only affects the class E airspace extending upward from 700 feet above the surface at Fitch H. Beach Airport and does not affect or impact any other airspace within the area. This amendment does not change the class of airspace, and therefore does not change any of the current

requirements on the pilot in command when operating at Fitch H. Beach Airport.

Due to a recent change to FAA Order 7400.2L, dated October 12, 2017, the name of the city associated with the airport is removed from the airspace legal designation.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace area extending upward from 700 feet above the surface within a 6.4-mile radius (increased from a 6.3-mile radius) at Fitch H. Beach, Charlotte, MI, and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

The name of the city associated with the airport is removed from the airspace legal designation to comply with a recent change to FAA Order 7400.2L. Except for the change noted above, this rule is the same as published in the NPRM.

Airspace reconfiguration is necessary due to the decommissioning of the Lansing VOR/TACAN, which provided navigation guidance for the instrument procedures to this airport, as part of the VOR MON Program. This action enhances safety and the management of IFR operations at this airport.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

AGL MI E5 Charlotte, MI [Amended]

Fitch H. Beach Airport, MI

(Lat. 42°34′27″ N, long. 84°48′44″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Fitch H. Beach Airport.

Issued in Fort Worth, Texas, on April 30, 2018.

Christopher L. Southerland,

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

[FR Doc. 2018–09562 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–1002; Airspace Docket No. 17–ACE–12]

RIN 2120–AA66

Amendment of Class E Airspace; Muscatine, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace designated as a surface area and Class E airspace extending upward from 700 feet above the surface at Muscatine Municipal Airport, Muscatine, IA. This action is required due to the decommissioning of the Port City VHF omnidirectional range (VOR) facility, which provided navigation guidance for the instrument procedures to this airport. The VOR has been decommissioned as part of the VOR Minimum Operational Network (MON) Program.

DATES: Effective 0901 UTC, July 19, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.* FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace designated as a surface area and Class E airspace extending upward from 700 feet above the surface at Muscatine Municipal Airport, Muscatine, IA, to support instrument flight rules (IFR) operations at the airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (82 FR 61698; December 29, 2017) for Docket No. FAA–2017–1002 to modify Class E airspace designated as a surface area and Class E airspace extending upward from 700 feet above the surface at Muscatine Municipal Airport, Muscatine, IA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6002 and 6005, respectively, of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA amends Title 14, Code of Federal Regulations (14 CFR) part 71 by:

Modifying Class E airspace designated as a surface area to within a 4.1-mile radius (increased from a 3.9-mile radius) of Muscatine Municipal Airport, Muscatine, IA, with an extension 1.0 mile either side of the 305° bearing from the airport from the 4.1-mile radius to 4.4 miles northwest of the airport, and an extension 1.0 mile either side of the 238° bearing from the airport from the 4.1-mile radius to 4.4 miles southwest of the airport. This action also makes an editorial change to the airspace legal description replacing ''Airport/Facility Directory'' with ''Chart Supplement''; and

Modifying Class E airspace extending upward from 700 feet above the surface at Muscatine Municipal Airport by removing the Port City VOR/DME from the airspace description, removing the extensions referencing the Port City VOR/DME, and adding an extension 3.8 miles either side of the 238° bearing from the airport from the 6.6-mile radius to 10.5 miles southwest of the airport.

Airspace reconfiguration is necessary due to the decommissioning of the Port City VOR as part of the VOR MON Program, and to bring the airspace and airspace descriptions into compliance with FAA Order 7400.2L, Procedures for Handling Airspace Matters. Controlled airspace is necessary for the safety and management of IFR operations at the airport.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ACE IA E2 Muscatine, IA [Amended]

Muscatine Municipal Airport, IA
(Lat. 41°22′04″ N, long. 91°08′54″ W)

Within a 4.1-mile radius of Muscatine Municipal Airport, and within 1.0 mile either side of the 305° bearing from the airport from the 4.1-mile radius to 4.4 miles northwest of the airport, and within 1.0 mile either side of the 238° bearing from the airport from the 4.1-mile radius to 4.4 miles southwest of the airport. This Class E airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

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

* * * * *

ACE IA E5 Muscatine, IA [Amended]

Muscatine Municipal Airport, IA
(Lat. 41°22′04″ N, long. 91°08′54″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile

radius of Muscatine Municipal Airport and within 3.8 miles either side of the 238° bearing from the airport from the 6.6-mile radius to 10.5 miles southwest of the airport.

Issued in Fort Worth, Texas, on April 25, 2018.

Christopher L. Southerland,

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

[FR Doc. 2018–09403 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0740; Airspace Docket No. 17–AGL–18]

RIN 2120–AA66

Amendment of Class E Airspace; Milwaukee, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Batten International Airport, Racine, WI, contained within the Milwaukee, WI, airspace description. This action is required due to the decommissioning of the Horlick VHF omnidirectional range (VOR) which provided navigation guidance for the standard instrument approach procedures to this airport. The Horlick VOR is being decommissioned as part of the VOR Minimum Operational Network (MON) Program. This action enhances the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, July 19, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace extending upward from 700 feet above the surface at Batten International Airport, Racine, WI, contained within the Milwaukee, WI, airspace description, to support IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (82 FR 44365; September 22, 2017) for Docket No. FAA–2017–0740 to modify Class E airspace extending upward from 700 feet above the surface at Batten International Airport, Racine, WI, contained within the Milwaukee, WI, airspace legal description. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace area extending upward from 700 feet above the surface to within a 6.6-mile radius (decreased from an 8.1-mile radius) at Batten International Airport, Racine, WI, contained within the Milwaukee, WI, airspace legal description.

Airspace reconfiguration is necessary due to the decommissioning of the Horlick VOR, which provided navigation guidance for the instrument procedures to this airport, as part of the VOR MON Program. This action enhances safety and the management of IFR operations at this airport.

The names of the cities associated with the airports listed in the Milwaukee, WI, airspace designation have been removed to comply with a recent change to FAA Order 7400.2L, Procedures for Handling Airspace Matters.

Except for the change noted above, this rule is the same as published in the NPRM.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

AGL WI E5 Milwaukee, WI [Amended]

General Mitchell International Airport, WI
(Lat. 42°56′49″ N, long. 87°53′49″ W)
Batten International Airport, WI
(Lat. 42°45′40″ N, long. 87°48′50″ W)
Waukesha County Airport, WI
(Lat. 43°02′28″ N, long. 88°14′13″ W)
Lawrence J. Timmerman Airport, WI
(Lat. 43°06′37″ N, long. 88°02′04″ W)

That airspace extending upward from 700 feet above the surface within an 8.4-mile radius of General Mitchell International Airport, and within a 6.6-mile radius of Batten International Airport, and within a 7.5-mile radius of Waukesha County Airport, and within 2 miles each side of the 282° bearing from Waukesha County Airport extending from the 7.5-mile radius to 10.5 miles west of Waukesha County Airport, and within an 8.9-mile radius of Lawrence J. Timmerman Airport.

Issued in Fort Worth, Texas, on April 30, 2018.

Christopher L. Southerland,

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

[FR Doc. 2018–09561 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2014–F–1509]

Food Additives Permitted in Feed and Drinking Water of Animals; Marine Microalgae

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of dried marine microalgae as a source of docosahexaenoic acid (DHA) for use in complete, dry foods for adult dogs. This action is in response to a food additive petition filed by DSM Nutritional Products.

DATES: This rule is effective May 7, 2018. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by June 6, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before June 6, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 6, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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–2014–F–1509 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Marine Microalgae.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in 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 objections. 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 objections and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–224), Rockville, MD 20855, 240–402–6729, *chelsea.trull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of October 16, 2014 (79 FR 62090), FDA announced that we had filed a food additive petition (animal use) (FAP 2288) submitted by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of *Schizochytrium* sp. dried marine microalgae as a source of DHA for use in complete, dry foods for adult dogs.

II. Conclusion

FDA concludes that the data establish the safety and utility of *Schizochytrium* sp. dried marine microalgae as a source of DHA for use in complete, dry foods for adult dogs and that the food additive regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order 12866.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Add § 573.615 to subpart B to read as follows:

§ 573.615 Marine microalgae.

The food additive, marine microalgae, may be safely used as a source of docosahexaenoic acid (DHA) and other omega-3 fatty acids in accordance with the following prescribed conditions:

(a) The additive is dried whole cells of nonviable, nontoxigenic, nonpathogenic *Schizochytrium* sp. algae grown as a pure culture.

(b) The additive is used in complete, dry adult maintenance food for dogs in accordance with good manufacturing and feeding practices not to exceed 16.5 pounds per ton (7.5 kilograms (kg) per 1000 kg) of complete, dry, adult maintenance dog food.

(c) The additive consists of not less than 17.0 percent (4*Z*,7*Z*,10*Z*,13*Z*,16*Z*,19*Z*)-docosa-4,7,10,13,16,19-hexaenoic acid (docosahexaenoic acid or DHA).

(d) The additive meets the following specifications:

(1) Not less than 40 percent crude fat;

(2) Not more than 12 percent ash;

(3) Not more than 8 percent unsaponifiable matter;

(4) Not more than 5 percent insoluble impurities;

(5) Not more than 5 percent free fatty acids; and

(6) Not more than 6 percent water.

(e) To ensure the safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed, shall contain the name of the additive, marine microalgae.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate that the maximum use level of the additive shall not exceed 16.5 pounds per ton (7.5 kg per 1000 kg) of complete, dry, adult maintenance dog food.

(ii) Adequate directions for use.

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09636 Filed 5–4–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA–2017–N–7007]

RIN 0910–AH49

Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of January 26, 2018, a direct final rule to amend the general biologics regulations relating to time of inspection requirements and to also remove duties of inspector requirements. The comment period closed April 11, 2018. FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

DATES: The direct final rule published at January 26, 2018 (83 FR 3586), is withdrawn effective May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on January 26, 2018 (83 FR 3586) is withdrawn.

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09589 Filed 5–4–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2018–0003]

RIN 1218–AB76

Revising the Beryllium Standard for General Industry

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Direct final rule; request for comment.

SUMMARY: On January 9, 2017, the Occupational Safety and Health Administration (OSHA) issued a final rule adopting a comprehensive general industry standard for exposure to beryllium and beryllium compounds. In this Direct Final Rule (DFR), OSHA is adopting a number of clarifying amendments to address the application of the standard to materials containing trace amounts of beryllium. OSHA believes this rule will maintain safety and health protections for workers while reducing the burden to employers of complying with the current rule.

DATES: This DFR will become effective on July 6, 2018 unless significant adverse comment is submitted (transmitted, postmarked, or delivered) by June 6, 2018. If DOL receives significant adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public that this DFR will not take effect (see Section III, ''Direct Final Rulemaking,'' for more details on this process). Comments to this DFR, hearing requests, and other information must be submitted (transmitted, postmarked, or delivered) by June 6, 2018. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: The public can submit comments, hearing requests, and other material, identified by Docket No. OSHA–2018–0003, using any of the following methods:

Electronically: Submit comments and attachments, as well as hearing requests and other information, electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments. Note that this docket may include several different **Federal Register** notices involving active rulemakings, so it is extremely important to select the correct notice or its ID number when submitting comments for this rulemaking. After accessing ''all documents and comments'' in the docket (OSHA–2018–0003), check the ''Rule'' box in the column headed ''Document Type,'' find the document posted on the date of publication of this document, and click the ''Submit a Comment'' link. Additional instructions for submitting comments are available from the *http://www.regulations.gov* homepage.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693–1648. OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (*e.g.,* studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Docket No. OSHA–2018–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. These attachments must clearly identify the sender's name, the date, the subject, and the docket number (OSHA–2018–0003) so that the Docket Office can attach them to the appropriate document.

Regular mail, express delivery, hand delivery, and messenger (courier) service: Submit comments and any additional material to the OSHA Docket Office, Docket No. OSHA–2018–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service. The Docket Office will accept deliveries (express delivery, hand delivery, messenger service) during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the Agency's name, the title of the rulemaking (Beryllium Standard: Direct Final Rule), and the docket number (OSHA–2018–0003). OSHA will place comments and other material, including any personal information, in the public docket without revision, and the comments and other material will be available online at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal

information (either about themselves or others), such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the above address. The electronic docket for this direct final rule established at *http://www.regulations.gov* contains most of the documents in the docket. However, some information (*e.g.,* copyrighted material) is not available publicly to read or download through this website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Mr. Frank Meilinger, OSHA Office of Communications, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3647, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information and technical inquiries: William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3718, 200 Constitution Avenue NW, Washington, DC 20210; telephone (202) 693–1950.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

On January 9, 2017, OSHA published its final rule Occupational Exposure to Beryllium and Beryllium Compounds in the **Federal Register** (82 FR 2470). OSHA concluded that employees exposed to beryllium and beryllium compounds at the preceding permissible exposure limits (PELs) were at significant risk of material impairment of health, specifically chronic beryllium disease and lung cancer. OSHA concluded that the new 8-hour time-weighted average (TWA) PEL of 0.2 μg/m^3 reduced this significant risk to the maximum extent feasible. Based on information submitted to the record, in the final rule OSHA issued three separate standards—general industry, shipyards, and construction. In addition to the revised PEL, the final rule established a new short-term exposure limit (STEL) of 2.0 μg/m^3 over a 15-minute sampling period and an action level of 0.1 μg/m^3 as an 8-hour TWA, along with a number of ancillary provisions intended to provide additional protections to employees, such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping similar to those found in other OSHA health standards.

This DFR amends the text of the beryllium standard for general industry to clarify OSHA's intent with respect to certain terms in the standard, including the definition of Beryllium Work Area (BWA), the definition of emergency, and the meaning of the terms dermal contact and beryllium contamination. It also clarifies OSHA's intent with respect to provisions for disposal and recycling and with respect to provisions that the Agency intends to apply only where skin can be exposed to materials containing at least 0.1% beryllium by weight.

This direct final rule is expected to be an Executive Order (E.O.) 13771 deregulatory action. Details on OSHA's cost/cost savings estimates for this direct final rule can be found in the rule's economic analysis. OSHA has estimated that, at a 3 percent discount rate over 10 years, there are net annual cost savings of $0.36 million per year for this direct final rule; at a discount rate of 7 percent, there are net annual cost savings of $0.37 million per year. When the Department uses a perpetual time horizon, the annualized cost savings of the direct final rule is $0.37 million with 7 percent discounting. While the 2017 Beryllium Final Rule went into effect on May 20, 2017, compliance obligations do not begin until May 11, 2018.

II. Consideration of Comments

OSHA will consider comments on all issues related to this action including economic or other regulatory impacts of this action on the regulated community. If OSHA receives no significant adverse comment, OSHA will publish a **Federal Register** document confirming the effective date of this DFR and withdrawing the companion Notice of Proposed Rulemaking (NPRM). Such confirmation may include minor stylistic or technical changes to the document. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of this DFR as the date of promulgation.

III. Direct Final Rulemaking

In direct final rulemaking, an agency publishes a DFR in the **Federal Register**, with a statement that the rule will go into effect unless the agency receives significant adverse comment within a specified period. The agency may publish an identical concurrent NPRM. If the agency receives no significant adverse comment in response to the DFR, the rule goes into effect. OSHA typically confirms the effective date of a DFR through a separate **Federal Register** document. If the agency receives a significant adverse comment, the agency withdraws the DFR and treats such comment as a response to the NPRM. An agency typically uses direct final rulemaking when an agency anticipates that a rule will not be controversial.

For purposes of this DFR, a significant adverse comment is one that explains why the amendments to OSHA's beryllium standard would be inappropriate. In determining whether a comment necessitates withdrawal of the DFR, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. OSHA will not consider a comment recommending an additional amendment to this rule to be a significant adverse comment unless the comment states why the DFR would be ineffective without the addition.

In addition to publishing this DFR, OSHA is publishing a companion NPRM in the **Federal Register**. The comment period for the NPRM runs concurrently with that of the DFR. OSHA will treat comments received on the companion NPRM as comments also regarding the DFR. Similarly, OSHA will consider significant adverse comment submitted to the DFR as comment to the companion NPRM. Therefore, if OSHA receives a significant adverse comment on either this DFR or the NPRM, it will withdraw this DFR and proceed with the companion NPRM. In the event OSHA withdraws the DFR because of significant adverse comment, OSHA will consider all timely comments received in response to the DFR when it continues with the NPRM. After carefully considering all comments to the DFR and the NPRM, OSHA will decide whether to publish a new final rule.

OSHA determined that the subject of this rulemaking is suitable for direct final rulemaking. This amendment to the standard is clarifying in nature and does not adversely impact the safety or health of employees. The amended standard will clarify OSHA's intent regarding certain terms in the standard, including the definition of Beryllium Work Area (BWA), the definition of emergency, and the meaning of the terms dermal contact and beryllium contamination. It will also clarify OSHA's intent with respect to provisions for disposal and recycling and with respect to provisions that the Agency intends to apply only where skin can be exposed to materials containing at least 0.1% beryllium by weight. The revisions do not impose any new costs or duties. For these reasons, OSHA does not anticipate objections from the public to this rulemaking action.

IV. Discussion of Changes

On January 9, 2017, OSHA adopted comprehensive standards addressing exposure to beryllium and beryllium compounds in general industry, construction, and shipyards. 82 FR 2470. Beryllium ''occurs naturally in rocks, soil, coal, and volcanic dust,'' but can cause harm to workers through exposure in the workplace. 80 FR 47579. OSHA has thus set a general industry exposure limit for beryllium and beryllium compounds since 1971, modified most recently in 2017. *See* 80 FR 47578–47579; 82 FR 2471. This DFR amends that 2017 general industry beryllium standard (codified at 29 CFR 1910.1024) to clarify its applicability to materials containing trace amounts of beryllium and to make related changes. This DFR does not affect the construction and shipyard standards, which are being addressed in a separate rulemaking. See 82 FR 29182.

During the last rulemaking, OSHA addressed the issue of trace amounts of beryllium. In its notice of proposed rulemaking, OSHA proposed to exempt from its beryllium standard materials containing less than 0.1% beryllium by weight on the premise that workers in exempted industries are not exposed at levels of concern, 80 FR 47775, but noted evidence of high airborne exposures in some of those industries, in particular the primary aluminum production and coal-fired power generation industries. 80 FR 47776. Therefore, OSHA proposed for comment several regulatory alternatives, including an alternative that would ''expand the scope of the proposed standard to also include all operations in general industry where beryllium exists only as a trace contaminant.'' 80 FR 47730. After receiving comment, OSHA adopted in the final rule an alternative limiting the exemption for materials containing less than 0.1% beryllium by weight to where the employer has objective data demonstrating that employee exposure to airborne beryllium will remain below the action level (AL) of 0.1 $\mu g/m^3$, measured as an 8-hour TWA, under any foreseeable conditions. 29 CFR 1910.1024(a)(2). In doing so, OSHA noted that the AL exception ensured that workers with airborne exposures of concern were covered by the standard:

> OSHA agrees with the many commenters and testimony expressing concern that materials containing trace amounts of beryllium (less than 0.1 percent by weight) can result in hazardous [airborne] exposures to beryllium. We disagree, however, with those who supported completely eliminating the exemption because this could have unintended consequences of expanding the scope to cover minute amounts of naturally occurring beryllium (Ex 1756 Tr. 55). Instead, we believe that alternative #1b—essentially as proposed by Materion and USW [United Steelworkers] and acknowledging that workers can have significant [airborne] beryllium exposures even with materials containing less than 0.1%—is the most appropriate approach. Therefore, in the final standard, it is exempting from the standard's application materials containing less than 0.1% beryllium by weight only where the employer has objective data demonstrating that employee [airborne] exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. 82 FR 2643.

As the regulatory history makes clear, OSHA intended to protect employees working with trace beryllium only when it caused airborne exposures of concern. OSHA did not intend for provisions aimed at protecting workers from the effects of dermal contact to apply in the case of materials containing only trace amounts of beryllium. Since the publication of the final rule, however, stakeholders have suggested that an unintended consequence of the final rule's revision of the trace exemption is that provisions designed to protect workers from dermal contact with beryllium-contaminated material could be read as applying to materials with only trace amounts of beryllium.

This DFR adjusts the regulatory text of the general industry beryllium standard to clarify that OSHA does not intend for requirements that primarily address dermal contact to apply in processes, operations, or areas involving only materials containing less than 0.1% beryllium by weight. These clarifications are made through changes to the definition of beryllium work area; the addition of definitions of dermal contact, beryllium-contaminated, and contaminated with beryllium; clarifications of certain hygiene provisions with respect to beryllium contamination; and the clarifications to provisions for disposal and recycling. In addition, because under these changes it is possible to have a regulated area that is not a beryllium work area, this DFR makes changes to certain housekeeping provisions to ensure they apply in all regulated areas. Finally, this DFR also includes a change to the definition of ''emergency'', adding detail to the definition so as to clarify the nature of the circumstances OSHA intends to be considered an emergency for the purposes of the standard.

Definition of beryllium work area. Paragraph (b) of the beryllium standard published in January 2017 defined a beryllium work area as any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. This DFR amends the definition as follows: ''Beryllium work area means any work area: (1) Containing a process or operation that can release beryllium and that involves materials that contain at least 0.1% beryllium by weight; and (2) where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.'' This change clarifies OSHA's intent that many of the provisions associated with beryllium work areas should only apply to areas where there are processes or operations involving materials at least 0.1% beryllium by weight.

Specifically, this change to the beryllium work area definition clarifies OSHA's intent that the following provisions associated with beryllium work areas do not apply where processes and operations involve only materials containing trace amounts of beryllium (less than 0.1% beryllium by weight): Establishing and demarcating beryllium work areas (paragraphs (e)(1)(i) and (e)(2)(i)); including procedures for minimizing cross-contamination within (paragraph (f)(1)(i)(D)) or minimizing migration of beryllium out of (paragraph (f)(1)(i)(F)) such areas in the written exposure control plan; ensuring that at least one engineering or process control is in place to reduce beryllium exposure where airborne beryllium levels meet or exceed the AL (revised paragraph

(f)(2)(ii)).[1] Additionally, for areas where beryllium is only present in materials at concentrations of less than 0.1% beryllium by weight, unless that area is also a regulated area, employers are not required to ensure that all surfaces in such areas are as free as practicable of beryllium (paragraph (j)(1)(i)); ensure that all surfaces in such areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure (paragraph (j)(2)(i)); or prohibit dry sweeping or brushing for cleaning surfaces in such areas (paragraph (j)(2)(ii)).

This DFR also includes conforming changes to maintain the January 2017 rule's requirements for housekeeping in regulated areas. Because all regulated areas were also beryllium work areas under the January 2017 beryllium standard, OSHA did not specify whether requirements for beryllium work areas should also apply in regulated areas (areas in which airborne beryllium exposure meets or exceeds the TWA PEL or STEL). This DFR's clarification to the definition of beryllium work area, however, means that it is possible for a work area to be a regulated area, but not a beryllium work area. This would occur when processes that involve only materials containing less than 0.1% beryllium by weight nevertheless create airborne beryllium exposures at or above the TWA PEL or STEL. 82 FR 2583. It is thus important to clarify that housekeeping (paragraph (j)) requirements continue to apply in regulated areas, even if the processes or operations in these areas involve materials with only trace beryllium. Operations or processes involving trace beryllium materials must generate extremely high dust levels in order to exceed the TWA PEL or STEL. Following the housekeeping methods required by paragraph (j) will help to protect workers against resuspension of surface beryllium accumulations from extremely dusty operations and limit workers' airborne exposure to beryllium.

The DFR accordingly amends paragraphs (j)(1)(i), (j)(2)(i), and (j)(2)(ii) to state explicitly that they apply to regulated areas, as follows. Paragraph (j)(1)(i), as amended, states that ''[t]he employer must maintain all surfaces in beryllium work areas and regulated areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard.'' Paragraph (j)(2)(i), as amended, states that ''[t]he employer must ensure that surfaces in beryllium work areas and regulated areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.'' Paragraph (j)(2)(ii), as amended, states that ''[t]he employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas or regulated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.''

This DFR also makes conforming changes to the engineering controls requirements to ensure that the hierarchy of controls continues to apply in all regulated areas. Paragraph (f)(2) of the January 2017 beryllium standard provided that, if airborne exposures still exceed the PEL or STEL after implementing at least one control for each operation in a beryllium work area that releases airborne beryllium, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the limit exceeded. OSHA intended this provision to apply to all operations within the scope of the standard that can release airborne beryllium. 82 FR 2671–72. Because, under this DFR's revisions, not all regulated areas will be beryllium work areas, this DFR rearranges the regulatory text of paragraph (f)(2) to make clear that the hierarchy of controls will continue to apply in regulated areas that are not beryllium work areas.

Definitions related to beryllium contamination. To further clarify OSHA's intent that the standard's requirements aimed at reducing the effect of dermal contact with beryllium should not apply to areas where there are no processes or operations involving materials containing at least 0.1% beryllium by weight, this DFR defines ''beryllium-contaminated or contaminated with beryllium'' and adds those terms to certain provisions in the standard. The DFR defines those terms as follows: ''Contaminated with beryllium and beryllium-contaminated mean contaminated with dust, fumes, mists, or solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight.'' The DFR adds the terms to certain provisions in the standard's requirements for hygiene areas and disposal and recycling.

The use of this definition accordingly clarifies OSHA's intent that the following provisions, which apply where clothing, hair, skin, or work surfaces are beryllium-contaminated, do not apply where the contaminating material contains less than 0.1% beryllium by weight: Paragraph (h)(2)(i) and paragraph (h)(2)(ii), which require the employer to ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the appropriate time and as specified in the written exposure control plan required by paragraph (f)(1); and paragraph (h)(2)(iii) and paragraph (h)(2)(iv), which require the employer to ensure that measures to prevent cross contamination between beryllium-contaminated personal protective clothing and equipment and street clothing are observed and that beryllium-contaminated personal protective clothing and equipment are not removed from the workplace. This DFR also amends paragraph (h)(3)(ii), which requires the employer to ensure that beryllium is properly removed from PPE, by adding the term ''beryllium-contaminated'' so that this requirement applies only where the contaminating material contains at least 0.1% beryllium by weight. The amended paragraph (h)(3)(ii) reads as follows: ''The employer must ensure that beryllium is not removed from beryllium-contaminated personal protective clothing and equipment by blowing, shaking, or any other means that disperses beryllium into the air.''

Similarly, the DFR's inclusion of the term ''contaminated with beryllium'' in paragraphs (i)(3)(i)(B) and (i)(3)(ii)(B) clarifies OSHA's intent that those provisions, which require employers to provide and ensure use of showers where employees' hair or body parts other than hands, face, and neck can reasonably be expected to become contaminated with beryllium, do not apply where the contaminating material contains less than 0.1% beryllium by weight.

The DFR's adoption of the definition of ''beryllium-contaminated'' further clarifies the application of certain requirements that are meant to minimize re-entrainment of airborne beryllium and reduce the effect of

[1] As explained in the preamble to the January 2017 rule, in industries that process or handle materials with only trace amounts of beryllium and that encounter exposures to beryllium above the action level, the PEL would ''be exceeded only during operations that generate [an] excessive amount of visible airborne dust.'' 82 FR 2583. OSHA therefore expects that if exposures in such a facility are below the PEL but above the AL, there is already at least one engineering or process control in place, so this requirement had no effect on primary aluminum production or coal-fired utilities. The 2017 FEA explained that this provision would only require additional controls in two job categories in two application groups, neither of which are in primary aluminum production or coal-fired utilities. (Document ID OSHA–H005C–2006–0870–2042, p. V–12).

dermal contact with beryllium. Specifically, it clarifies that paragraph (j)(2)(iii), which prohibits the use of compressed air for cleaning beryllium-contaminated surfaces except where used in conjunction with an appropriate ventilation system, and paragraph (j)(2)(iv), which requires the use of respiratory protection and PPE in accordance with paragraphs (g) and (h) of the standard when dry sweeping, brushing, or compressed air are used to clean beryllium-contaminated surfaces, do not apply where the contaminating material contains less than 0.1% beryllium by weight. OSHA does not expect the additional airborne exposure from dry brushing, sweeping, or using compressed air to significantly increase the levels of airborne exposure outside regulated areas when working with trace beryllium. This is because for trace beryllium to generate airborne exposures of concern, excessive amounts of dust would need to be generated, and this would not happen outside of regulated areas.

This DFR also adds the term ''beryllium-contaminated'' to certain requirements pertaining to eating and drinking areas to clarify that hygiene requirements in these areas apply only where materials containing more than 0.1% beryllium by weight may contaminate such areas. Paragraph (i)(4)(i), as amended by this DFR, states that wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that ''[b]eryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium.'' Paragraph (i)(4)(ii), as amended by this DFR, requires employers to ensure that ''[n]o employees enter any eating or drinking area with beryllium-contaminated personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body.''

Definition of dermal contact with beryllium. To clarify OSHA's intent that requirements of the standard associated with dermal contact with beryllium should not apply to areas where there are no processes or operations involving materials at least 0.1% beryllium by weight, this DFR also adds a definition for dermal contact with beryllium. This new definition provides, ''Dermal contact with beryllium means skin exposure to: (1) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight; (2) solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight; or (3) dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight.'' Accordingly, the definition clarifies that paragraph (h)(1)(ii), which requires an employer to provide and ensure the use of personal protective clothing and equipment where there is a reasonable expectation of dermal contact with beryllium, applies only where contact may occur with materials containing at least 0.1% beryllium by weight. This definition also clarifies that the requirements related to dermal contact in the written exposure control plan, washing facilities, medical examinations, and training provisions only apply where contact may occur with materials containing at least 0.1% beryllium by weight.

Definition of emergency. This DFR also clarifies the definition of ''emergency'' in paragraph (b) of the beryllium standard published in January 2017. That paragraph defined an emergency as ''any uncontrolled release of airborne beryllium.'' This DFR amends the definition as follows: ''Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an uncontrolled and unintended release of airborne beryllium that presents a significant hazard.'' This change clarifies the circumstances under which the provisions associated with emergencies should apply, including the requirements that employers provide and ensure employee use of respirators and that employers provide medical surveillance to employees exposed in an emergency. This change is consistent with OSHA's intent as explained in the preamble to the 2017 final rule. 82 FR 2690 (''An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes.''). These examples show OSHA's intent to define an ''emergency'' as something unintended as well as uncontrolled, and including the examples in the new definition make that clear. It is also consistent with other OSHA standards, such as methylenedianiline (1910.1050), vinyl chloride (1910.1017), acrylonitrile (1910.1045), benzene (1910.1028), and ethylene oxide (1910.1047).

Disposal and recycling. Finally, this DFR clarifies the application of the disposal and recycling provisions. Paragraph (j)(3) of the beryllium standard published in January 2017 required employers to ensure that materials designated for disposal that contain or are contaminated with beryllium are disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of the standard. It also required that materials designated for recycling which contain or are contaminated with beryllium are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of the standard, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of the standard. These provisions were designed to protect workers from dermal contact with beryllium dust generated during processing, where there is a risk of beryllium sensitization. See 82 FR 2694, 2695. This DFR accordingly limits those requirements to ''materials that contain beryllium in concentrations of 0.1 percent by weight or more or are contaminated with beryllium,'' consistent with OSHA's intention that provisions aimed at protecting workers from the effects of dermal contact do not apply in the case of materials containing only trace amounts of beryllium. The hazard communication standard continues to apply according to its terms. See 29 CFR 1910.1200.

V. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970) (''OSH Act''; 29 U.S.C. 651 *et seq.*) is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 655(b), 658. A safety or health standard is a standard that ''requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate when a significant risk of material harm exists in the workplace and the standard would substantially reduce or eliminate that workplace risk. See *Industrial Union Dept., AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 641–42 (1980) (plurality opinion).

OSHA need not make additional findings on risk for this DFR. As discussed above, this DFR will not diminish the employee protections put into place by the standard being amended. And because OSHA previously determined that the

beryllium standard substantially reduces a significant risk (82 FR 2545–52), it is unnecessary for the Agency to make additional findings on risk for the minor changes and clarifications being made to the standard. See, *e.g., Public Citizen Health Research Group* v. *Tyson,* 796 F.2d 1479, 1502 n.16 (D.C. Cir. 1986) (rejecting the argument that OSHA must ''find that each and every aspect of its standard eliminates a significant risk'').

OSHA has determined that these minor changes and clarifications are technologically and economically feasible. All OSHA standards must be both technologically and economically feasible. See *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1264 (D.C. Cir. 1980) (''*Lead I*''). The Supreme Court has defined feasibility as ''capable of being done.'' *Am. Textile Mfrs. Inst.* v. *Donovan,* 452 U.S. 490, 509–10 (1981) (''*Cotton Dust*''). Courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility, ''within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.'' *Lead I,* 647 F.2d at 1272. With respect to economic feasibility, courts have held that ''a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry.'' *Id.* at 1265 (internal quotation marks and citations omitted). In the final economic analysis (FEA) for the 2017 beryllium rule, OSHA concluded that the rule was economically and technologically feasible. OSHA has determined that this DFR is also economically and technologically feasible, because it does not impose any new requirements or costs.

VI. Final Economic Analysis and Regulatory Flexibility Act Certification

Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)) require that OSHA estimate the benefits, costs, and net benefits of regulations, and analyze the impacts of certain rules that OSHA promulgates. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This DFR is not an ''economically significant regulatory action'' under Executive Order 12866, or a ''major rule'' under the Congressional Review Act (5 U.S.C. 801 *et seq.*), and its impacts do not trigger the analytical requirements of UMRA. Neither the benefits nor the costs of this DFR would exceed $100 million in any given year. This DFR would, however, result in a net cost savings for employers in primary aluminum production and coal-fired utilities, which are the only industries in General Industry covered by the 2017 Beryllium Final Rule that OSHA identified with operations involving materials containing only trace beryllium (less than 0.1% beryllium by weight).

Several calculations illustrate the expected cost savings. At a discount rate of 3 percent, this DFR would yield annualized cost savings of $0.36 million per year for 10 years. At a discount rate of 7 percent, this DFR would yield an annualized cost savings of $0.37 million per year for 10 years. These net cost savings amount to approximately 0.6 percent of the original estimated cost of the 2017 Beryllium Final Rule for General Industry at discount rates of either 3 or 7 percent; to approximately 5.3 percent of the original estimated cost of the 2017 Beryllium Final Rule for primary aluminum production and coal-fired utilities only at a discount rate of 3 percent and 5.2 percent of the original estimated cost of the 2017 Beryllium Final Rule for primary aluminum production and coal-fired utilities only at a discount rate of 7 percent.[2] Under a perpetual time horizon, the annualized cost savings of this DFR is $0.37 million at a discount rate of 7 percent.

1. Changes to the Baseline: Updating to 2017 Dollars and Removing Familiarization Costs

Because baseline costs typically reflect the costs of compliance *without* the changes set forth in an agency's action—in this case, the DFR—OSHA has revised the baseline costs, as displayed in the FEA in support of the beryllium standard of January 9, 2017, in two ways. First, OSHA updated the projected costs for general industry contained in the FEA that accompanied the rule from 2015 to 2017 dollars, using the latest Occupational Employment Statistics (OES) wage data (for 2016) and inflating them to 2017 dollars. Second, OSHA excluded certain familiarization costs, included in the cost estimates developed in the beryllium FEA for the 2017 Beryllium Final Rule, because OSHA expects that those costs have already been incurred by affected employers. Thus, the baseline costs for this FEA are the projected costs from the 2017 FEA, updated to 2017 dollars, less familiarization costs in the 2017 beryllium final rule (but including some new familiarization costs for employers to become familiar with the revised provisions). Throughout this analysis of costs and cost savings, the context is limited to employers in primary aluminum production and coal-fired utilities.

2. Discussion of Overhead Costs

As in the 2017 FEA, OSHA has not accounted for overhead labor costs in its analysis of the cost savings for this DFR due to concerns about consistency. There are several ways to look at the cost elements that fit the definition of overhead, and there is a range of overhead estimates currently used within the federal government—for example, the Environmental Protection Agency has used 17 percent,[3] and government contractors have been reported to use an average of 77 percent.[4] Some overhead costs, such as advertising and marketing, may be more closely correlated with output than with labor. Other overhead costs vary with the number of new employees. For example, rent or payroll processing costs may change little with the addition of 1 employee in a 500-employee firm, but may change substantially with the addition of 100 employees. If an employer is able to rearrange current employees' duties to implement a rule, then the marginal share of overhead costs, such as rent, insurance, and major office equipment (*e.g.,* computers, printers, copiers) would be very difficult to measure with accuracy.

If OSHA had included an overhead rate when estimating the marginal cost of labor, without further analyzing an appropriate quantitative adjustment, and adopted for these purposes an overhead rate of 17 percent on base wages, the cost savings of this DFR

[2] The original estimated cost of the 2017 beryllium final rule for General Industry, and separately for primary aluminum production and coal-fired utilities, was updated to 2017 dollars and additionally adjusted and corrected, as subsequently explained in the text.

[3] See Grant Thornton LLP. 2015 Government Contractor Survey (Document ID OSHA–H005C–2006–0870–2153). The application of this overhead rate was based on an approach used by the Environmental Protection Agency, as described in EPA's ''Wage Rates for Economic Analyses of the Toxics Release Inventory Program,'' June 10, 2002. This analysis itself was based on a survey of several large chemical manufacturing plants: Heiden Associates, Final Report: A Study of Industry Compliance Costs Under the Final Comprehensive Assessment Information Rule, Prepared for the Chemical Manufacturers Association, December 14, 1989.

[4] For further examples of overhead cost estimates, please see the Employee Benefits Security Administration's guidance at *https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf.*

would increase to approximately $0.39 million per year, at discount rates of either 3 percent or 7 percent.[5] The addition of 17 percent overhead on base wages would therefore increase cost savings by approximately 7 percent above the primary estimate at either discount rate.

3. Cost Impact of the Changes to the Standard

OSHA estimates a net cost savings from this DFR for employers at primary aluminum production and coal-fired utilities, which again are the only two industries identified in the 2017 FEA as having costs associated with exposure to trace beryllium materials.[6] Annualizing the present value of net cost savings over ten years, the result is an annualized net cost savings of $0.36 million per year at a discount rate of 3 percent, or $0.37 million per year at a discount rate of 7 percent. When the Department uses a perpetual time horizon, the annualized net cost savings of this DFR is $0.37 million at a discount rate of 7 percent.

The undiscounted cost savings by provision and year are presented below in Table 1, and the cost savings by provision and discount rate are shown below in Tables 2 and 3. As described elsewhere in this document, the cost savings described in this FEA reflect savings only for provisions covered by the changes in this DFR as well as added familiarization costs. OSHA estimated no cost savings for the PEL, respiratory protection, exposure assessment, regulated areas, medical surveillance, medical removal protection, written exposure control plan, or training provisions because the DFR makes no changes of substance to those provisions.

[5] OSHA used an overhead rate of 17 percent on base wages in a sensitivity analysis in the FEA (OSHA–2010–0034–4247, p. VII–65) in support of the March 25, 2016 final respirable crystalline silica standards (81 FR 16286) and in the PEA in support of the June 27, 2017 proposed beryllium standards in construction and shipyard sectors (82 FR 29201).

[6] As noted in Section IV of this preamble, coverage of dermal contact with trace beryllium materials was an unintended consequence of OSHA's decision to cover airborne exposures to beryllium above the action level caused by operations that generate excessive amounts of dust from trace beryllium materials. Likewise, in the 2017 FEA supporting OSHA's Beryllium Final Rule, through an oversight, OSHA made no distinction between trace and non-trace beryllium materials when determining the cost of requirements triggered by dermal contact with beryllium. The cost savings generated by this FEA are a result of correcting these oversights.

a. Beryllium work areas. OSHA is limiting the definition of ''beryllium work area'' to any work area containing a process or operation ''that involves materials that contain at least 0.1% beryllium by weight. . . .'' OSHA has determined that affected establishments in primary aluminum production and coal-fired utilities would thus no longer need to designate and demarcate beryllium work areas because their materials would not meet that threshold outside of the ''regulated areas'' in primary aluminum production where employee exposures to airborne beryllium would exceed the PEL. In its previous economic analysis, OSHA had estimated that each of the establishments in these categories required beryllium work areas in addition to ''regulated areas,'' which were costed separately. The removal of these beryllium work area designations results in an annualized cost savings of $12,913 using a 3 percent discount rate and $15,682 using a 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

b. Protective work clothing and equipment. OSHA is recognizing no cost savings in this DFR for the elimination of PPE requirements associated with dermal contact in coal-fired utilities. In its 2017 FEA, OSHA listed the PPE compliance rate for utility workers at coal-fired utilities at 75 percent and therefore estimated PPE costs for the residual 25 percent of utility workers in the industry (where airborne exposures exceed the PEL or STEL or where there is dermal contact with beryllium). But upon further review, OSHA has determined that it should not have included those costs because affected employers in coal-fired utilities were already required to wear PPE under 29 CFR 1910.1018(j) to prevent skin and eye irritation from exposure to trace inorganic arsenic found in coal ash. As OSHA noted in its technological feasibility analysis, inorganic arsenic is often found in coal fly ash in ''concentrations 10 to 1,000 times greater than beryllium,'' fly ash is the primary source of beryllium exposure for employees in coal-fired utilities, and employers in this application group indicated that they were already following a majority of the provisions of the rule to comply with OSHA requirements for other hazardous substances, such as arsenic (p. IV–652). Thus, in all of the areas within a facility in which employees are likely to be exposed to beryllium, they are also likely to be exposed to concentrations of arsenic significantly high so as to trigger the arsenic PPE requirements. Accordingly, coal-fired utility compliance rates with the PPE requirement for affected workers should have been 100 percent in the prior FEA, and no costs for PPE for these workers should have been included in OSHA's cost estimates. Because OSHA should not have included new beryllium PPE costs for this group, OSHA is recognizing no cost savings in this DFR for the elimination of PPE requirements associated with dermal contact in coal-fired utilities.

There are, however, some small PPE cost savings for primary aluminum production. The January 2017 rule requires employers to provide PPE in two situations: (1) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; and (2) where there is a reasonable expectation of dermal contact with beryllium. 29 CFR 1910.1024(h)(1). It is the second of these two situations which OSHA believes will trigger cost savings. Because this DFR clarifies that ''dermal contact with beryllium'' does not include contact with beryllium in concentrations less than 0.1% beryllium by weight, gloves and other PPE requirements will be triggered by a reasonable expectation of dermal contact only with materials containing more than 0.1% beryllium by weight. In primary aluminum production, there is no dermal contact with materials containing beryllium above this threshold. As a result, the Agency has determined that in primary aluminum production, additional PPE is only necessary for workers exposed over the PEL. This change results in an annualized cost savings for employers in primary aluminum production of $35,023 using a 3 or 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

c. Hygiene areas and practices. The DFR's adoption of a definition for ''contaminated with beryllium'' also reduces the costs of complying with the Hygiene Areas and Practices provision in primary aluminum production (the costs for coal-fired utilities would not be affected). The 2017 Final Beryllium Rule requires employers to provide showers where both of two conditions are met:

(A) Airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; and

(B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck.

29 CFR 1910.1024(i)(3)(i). By revising (B) to incorporate the newly defined term ''contaminated with beryllium,'' the condition in paragraph (B) will not be met in primary aluminum production because no employees in this application group can reasonably be expected to become ''contaminated with beryllium.'' Thus, the beryllium standard does not require employers in this application group to provide showers. Similarly, employers need not provide the estimated lower-cost alternative of head coverings, discussed in the 2017 FEA.[7] Removing the cost of head coverings for workers in this application group results in an annualized cost savings for employers in primary aluminum production of $415 using a 3 or 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

d. Housekeeping. Similar to the above discussion about PPE in coal-fired utilities, OSHA is recognizing no cost savings in this DFR for coal-fired utilities as a result of the modification of the housekeeping requirements. In the FEA in support of the 2017 Beryllium Final Rule, the Agency listed the housekeeping compliance rate for affected workers at coal-fired utilities at 75 percent and therefore estimated housekeeping costs for the residual 25 percent of utility workers in a beryllium work area. But upon further review, OSHA has determined that affected employers in coal-fired utilities were already required to perform comparable housekeeping duties under 29 CFR 1910.1018(k) to prevent accumulations of inorganic arsenic found in coal ash. Accordingly, coal-fired utility compliance rates with the housekeeping requirements for affected workers should have been 100 percent in the prior FEA, and no costs for housekeeping for these workers should have been included in OSHA's cost estimates. Consequently, OSHA is recognizing no cost savings in this DFR for coal-fired utilities as a result of the modification of the housekeeping requirements.

The rule clarification also means that employers in primary aluminum production facilities will typically only be required to comply with the beryllium housekeeping provisions in ''regulated areas,'' which for cost purposes OSHA identified as employees exposed over the PEL in its exposure profile. There are several exceptions, none of which have a quantifiable impact on costs: Employers in this industry would still need to follow the housekeeping requirements when cleaning up spills and emergency releases of beryllium (paragraph (j)(1)(ii)), handling and maintaining cleaning equipment (paragraph (j)(2)(v)), and when necessary to reduce some workers exposures below the PEL (serving as an engineering control to prevent over-exposure to beryllium within regulated areas or the need for regulated areas). OSHA did not identify separate costs in its prior FEA for this use of housekeeping as a form of engineering control and does not do so here. Thus, for cost calculation purposes in this new FEA, OSHA removed housekeeping costs for all employees exposed below the PEL in its exposure profile. This change results in an annualized cost savings for employers in primary aluminum production of $323,664 using a 3 percent discount rate and $330,324 using a 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3. OSHA believes that these estimated cost savings might be slightly overstated to the extent that some housekeeping outside of the regulated areas will still be needed to perform an engineering-control function in some facilities, but the Agency is unable to quantify them now because of the variability among facilities and controls that employers may implement to comply with the standard.

e. Additional familiarization. In the FEA in support of OSHA's 2017 Beryllium Final Rule, the Agency determined that employers would need to spend time familiarizing themselves with the rule and allocated 4, 8, and 40 hours, depending on establishment size (fewer than 20 employees, between 20 and 499 employees, and 500 or more employees, respectively). OSHA has similarly determined that establishments will need to spend time familiarizing themselves with this DFR. As the affected provisions in this DFR are only a fraction of all the provisions in the 2017 final rule and would not require any new actions on the part of employers, the Agency has estimated familiarization time of 2, 4, and 20 hours per employer, depending on establishment size, for a supervisor to review the changes to the beryllium rule reflected in this DFR. This results in an annualized cost of $9,404 using a 3 percent discount rate and $11,421 using a 7 percent discount rate. Annualized costs by provision and discount rate—3 and 7 percent—can be seen below in Tables 2 and 3, respectively.

f. Unchanged provisions. As discussed earlier, this DFR primarily serves to clarify OSHA's intent with respect to certain terms and requirements in OSHA's 2017 beryllium general industry standard. These changes largely deal with clarifying the application of various requirements to trace beryllium. The triggers for most provisions in the standard—the PEL, respiratory protection, exposure assessment, regulated areas, medical surveillance, medical removal protection, written exposure control plan, and training provisions[8]—are determined by factors other than beryllium concentration and are unchanged by this DFR. Similarly, the revised definition of ''emergency'' in this DFR would not affect the costs estimated for the other provisions in the standard.

4. Economic and Technological Feasibility

In the FEA for the 2017 beryllium standard, OSHA concluded that the rule was economically and technologically feasible. This DFR does not impose any new requirements and has the net impact of removing a small amount of cost, so OSHA has determined that this final rule is also economically and technologically feasible.

[7] In the previous FEA, OSHA had included costs for head coverings in lieu of showers, reasoning that employees could avoid the need for showers because the head coverings and other PPE would prevent their hair or body parts from becoming contaminated with beryllium.

[8] While the changes in the standard do not mandate any additional employee training, OSHA notes that it had previously accounted for costs of annual re-training required by the standard (Document ID OSHA–H005C–2006–0870–2042, p. V–221).

5. Effects on Benefits

This DFR clarifies aspects of the 2017 general industry beryllium standard to address unintended consequences regarding the applicability of provisions designed to protect workers from dermal contact with beryllium-containing materials and trace amounts of beryllium. This DFR makes clear that OSHA did not, and does not, intend to apply the provisions aimed at protecting workers from the effects of dermal contact to industries that only work with beryllium in trace amounts where there is limited or no airborne exposure. In the prior FEA, OSHA did not identify any quantifiable benefits from avoiding beryllium sensitization from dermal contact (see discussion at p. VII–16 through VII–18). Thus, the revisions in this DFR, which are focused on dermal contact, do not have any impact on OSHA's previous benefit estimates.

6. Regulatory Flexibility Act Certification

This DFR will result in cost savings for affected small entities, and those savings fall below levels that could be said to have a significant positive economic impact on a substantial number of small entities.[9] Therefore, OSHA certifies that this direct final rule would not have a significant impact on a substantial number of small entities.

[9] OSHA investigated whether the projected cost savings would exceed 1 percent of revenues or 5 percent of profits for small entities and very small entities for every industry. To determine if this was the case, OSHA returned to its original regulatory flexibility analysis (in the 2017 FEA) for small entities and very small entities. OSHA found that the cost savings of this DFR are such a small percentage of revenues and profits for every affected industry that OSHA's criteria would not be exceeded for any industry.

TABLE 1—TOTAL UNDISCOUNTED NET COST SAVINGS OF THE FINAL BERYLLIUM STANDARD BY YEAR

[2017 Dollars]

Application group	Year									
	1	2	3	4	5	6	7	8	9	10
Aluminum Production	$613,367	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053
Coal Fired Utilities	9,461	0	0	0	0	0	0	0	0	0
Total	622,828	328,053	328,053	328,053	328,053	328,053	328,053	328,053	328,053	328,053

TABLE 2—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE FINAL BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY

[In 2017 dollars using a 3 percent discount rate]

Application group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	Housekeeping	Training	Total program costs
Aluminum Production													
331313	Alumina Refining and Primary Aluminum Production.	−$240	$0	$0	$2,639	$0	$0	$0	$35,023	$415	$323,664	$0	$361,500
Coal Fired Utilities													
221112	Fossil Fuel Electric Power Generation.	−6,209	0	0	8,087	0	0	0	0	0	0	0	1,878
311221	Wet Corn Milling	−282	0	0	260	0	0	0	0	0	0	0	−22
311313	Beet Sugar Manufacturing	−353	0	0	303	0	0	0	0	0	0	0	−49
311942	Spice and Extract Manufacturing.	−41	0	0	43	0	0	0	0	0	0	0	2
312120	Breweries	−54	0	0	43	0	0	0	0	0	0	0	−11
321219	Reconstituted Wood Product Manufacturing.	−20	0	0	22	0	0	0	0	0	0	0	2
322110	Pulp Mills	−32	0	0	22	0	0	0	0	0	0	0	−10
322121	Paper (except Newsprint) Mills.	−437	0	0	238	0	0	0	0	0	0	0	−199
322122	Newsprint Mills	−705	0	0	519	0	0	0	0	0	0	0	−186
322130	Paperboard Mills	−447	0	0	346	0	0	0	0	0	0	0	−101
325211	Plastics Material and Resin Manufacturing.	−85	0	0	87	0	0	0	0	0	0	0	2
325611	Soap and Other Detergent Manufacturing.	−23	0	0	22	0	0	0	0	0	0	0	−1
327310	Cement Manufacturing	−39	0	0	43	0	0	0	0	0	0	0	4
333111b	Farm Machinery and Equipment Manufacturing.	−24	0	0	22	0	0	0	0	0	0	0	−2
336510b	Railroad Rolling Stock Manufacturing.	−26	0	0	22	0	0	0	0	0	0	0	−4
611310	Colleges, Universities, and Professional Schools.	−387	0	0	195	0	0	0	0	0	0	0	−193
Total:													
General Industry Subtotal.		−9,404	0	0	12,913	0	0	0	35,023	415	323,664	0	362,610
Construction Subtotal.		0	0	0	0	0	0	0	0	0	0	0	0

TABLE 2—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE FINAL BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY—Continued

[In 2017 dollars using a 3 percent discount rate]

Application group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	Housekeeping	Training	Total program costs
Maritime Subtotal.	0	0	0	0	0	0	0	0	0	0	0	0	
Total, All Industries.	−9,404	0	0	12,913	0	0	0	35,023	415	323,664	0	362,610	

TABLE 3—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE FINAL BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY

[In 2017 dollars using a 7 percent discount rate]

Application Group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	Housekeeping	Training	Total program costs
Aluminum Production													
331313	Alumina Refining and Primary Aluminum Production.	−$291	$0	$0	$3,205	$0	$0	$0	$35,023	$415	$330,324	$0	$368,675
Coal Fired Utilities													
221112	Fossil Fuel Electric Power Generation.	−7,541	0	0	9,822	0	0	0	0	0	0	0	2,281
311221	Wet Corn Milling	−342	0	0	315	0	0	0	0	0	0	0	−27
311313	Beet Sugar Manufacturing	−428	0	0	368	0	0	0	0	0	0	0	−60
311942	Spice and Extract Manufacturing.	−50	0	0	53	0	0	0	0	0	0	0	3
312120	Breweries	−66	0	0	53	0	0	0	0	0	0	0	−13
321219	Reconstituted Wood Product Manufacturing.	−24	0	0	26	0	0	0	0	0	0	0	3
322110	Pulp Mills	−39	0	0	26	0	0	0	0	0	0	0	−12
322121	Paper (except Newsprint) Mills.	−531	0	0	289	0	0	0	0	0	0	0	−242
322122	Newsprint Mills	−856	0	0	631	0	0	0	0	0	0	0	−225
322130	Paperboard Mills	−543	0	0	421	0	0	0	0	0	0	0	−123
325211	Plastics Material and Resin Manufacturing.	−103	0	0	105	0	0	0	0	0	0	0	2
325611	Soap and Other Detergent Manufacturing.	−28	0	0	26	0	0	0	0	0	0	0	−2
327310	Cement Manufacturing	−48	0	0	53	0	0	0	0	0	0	0	5
333111b	Farm Machinery and Equipment Manufacturing.	−29	0	0	26	0	0	0	0	0	0	0	−3
336510b	Railroad Rolling Stock Manufacturing.	−31	0	0	26	0	0	0	0	0	0	0	−5
611310	Colleges, Universities, and Professional Schools.	−471	0	0	237	0	0	0	0	0	0	0	−234
Total: General Industry Subtotal.	−11,421	0	0	15,682	0	0	0	35,023	415	330,324	0	370,022	

Construction Subtotal.	0	0	0	0	0	0	0	0	0	0	0	0	
Maritime Subtotal.	0	0	0	0	0	0	0	0	0	0	0	0	
Total, All Industries.	−11,421	0	0	15,682	0	0	0	35,023	415	330,324	0	370,022	

VII. OMB Review Under the Paperwork Reduction Act of 1995

This rule contains no information collection requirements subject to OMB approval under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations at 5 CFR part 1320. The PRA defines a *collection of information* as *the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.* See 44 U.S.C. 3502(3)(A). While not affected by this rulemaking, the Department has cleared information collections related to occupational exposure to beryllium standards—general industry, 29 CFR 1910.1024; construction, 29 CFR 1926.1124; and shipyards, 29 CFR 1915.1024—under control number 1218–0267. The existing approved information collections are unchanged by this rulemaking. The Department welcomes comments on this determination.

VIII. Federalism

OSHA reviewed this DFR in accordance with the Executive Order on Federalism (E.O. 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when clear constitutional and statutory authority exists and the problem is national in scope. E.O. 13132 provides for preemption of State law only with the expressed consent of Congress. Any such preemption is to be limited to the extent possible.

Under Section 18 of the OSH Act, 29 U.S.C. 651 *et seq.,* Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as ''State Plan States'' (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State Plan States are free to develop and enforce under State law their own requirements for safety and health standards.

This DFR complies with E.O. 13132. In States without OSHA approved State Plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, this DFR would limit State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA approved State Plans, this rulemaking does not significantly limit State policy options.

IX. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 28 States and U.S. Territories with their own OSHA approved occupational safety and health plans (''State Plan States'') must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.,* because an existing State standard covering this area is ''at least as effective'' as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, must be applicable to both the private and public (State and local government employees) sectors, and must be completed within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States are not required to amend their standards, although the Agency may encourage them to do so. The 28 States and U.S. Territories with OSHA approved occupational safety and health plans are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming; Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands have OSHA approved State Plans that apply to State and local government employees only.

This DFR clarifies requirements and addresses the unintended consequences associated with provisions intended to address the effects of dermal contact with beryllium as applied to trace beryllium. It imposes no new requirements. Therefore, no new State standards would be required beyond those already required by the promulgation of the January 2017 beryllium standard for general industry. State-Plan States may nonetheless choose to conform to these revisions.

X. Unfunded Mandates Reform Act

OSHA reviewed this DFR according to the Unfunded Mandates Reform Act of 1995 (''UMRA''; 2 U.S.C. 1501 *et seq.*) and Executive Order 12875 (58 FR 58093). As discussed above in Section VI (''Economic Analysis and Regulatory Flexibility Certification'') of this preamble, the Agency determined that this DFR does not impose significant additional costs on any private- or public-sector entity. Accordingly, this DFR does not require significant additional expenditures by either public or private employers.

As noted above under Section IX (''State-Plan States''), the Agency's standards do not apply to State and local governments except in States that have elected voluntarily to adopt a State Plan approved by the Agency. Consequently, this DFR does not meet the definition of a ''Federal intergovernmental mandate'' (see Section 421(5) of the UMRA (2 U.S.C. 658(5))). Therefore, for the purposes of the UMRA, the Agency certifies that this DFR does not mandate that State, local, or Tribal governments adopt new, unfunded regulatory obligations. Further, OSHA concludes that the rule would not impose a Federal mandate on the private sector in excess of $100 million (adjusted annually for inflation) in expenditures in any one year.

List of Subjects in 29 CFR Part 1910

Beryllium, General industry, Health, Occupational safety and health.

Signed at Washington, DC, on April 27, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons stated in the preamble, OSHA amends 29 CFR part 1910 as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—Toxic and Hazardous Substances

■ 1. The authority section for subpart Z of part 1910 continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657) Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 5101 *et seq.*

■ 2. Amend § 1910.1024 as follows:

■ a. Revise the definition of ''Beryllium work area'' in paragraph (b);
■ b. Add definitions for ''Contaminated with beryllium and beryllium-contaminated'' and ''Dermal contact with beryllium'' in alphabetical order in paragraph (b);
■ c. Revise the definition of ''Emergency'' in paragraph (b);
■ d. Revise paragraph (f)(2);
■ e. Revise paragraph (h)(3)(ii);
■ f. Revise paragraphs (i)(3)(i)(B), (i)(3)(ii)(B), (i)(4)(i) and (ii); and
■ g. Revise paragraphs (j)(1)(i), (j)(2)(i) and (ii), and (j)(3).

The revisions and additions read as follows:

§ 1910.1024 Beryllium.

* * * * *

(b) * * *

Beryllium work area means any work area:

(i) Containing a process or operation that can release beryllium and that involves material that contains at least 0.1 percent beryllium by weight; and

(ii) Where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.

* * * * *

Contaminated with beryllium and beryllium-contaminated mean contaminated with dust, fumes, mists, or solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight.

Dermal contact with beryllium means skin exposure to:

(i) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight;

(ii) Solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight; or

(iii) Dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight.

* * * * *

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an uncontrolled and unintended release of airborne beryllium that presents a significant hazard.

* * * * *

(f) * * *

(2) *Engineering and work practice controls.* (i) The employer must use engineering and work practice controls to reduce and maintain employee airborne exposure to beryllium to or below the PEL and STEL, unless the employer can demonstrate that such controls are not feasible. Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs with engineering and work practice controls, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls using respiratory protection in accordance with paragraph (g) of this standard.

(ii) For each operation in a beryllium work area that releases airborne beryllium, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(iii) An employer is exempt from using the controls listed in paragraph (f)(2)(ii) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

* * * * *

(h) * * *

(3) * * *

(ii) The employer must ensure that beryllium is not removed from beryllium-contaminated personal protective clothing and equipment by blowing, shaking, or any other means that disperses beryllium into the air.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(B) Employee's hair or body parts other than hands, face, and neck can reasonably be expected to become contaminated with beryllium.

(ii) * * *

(B) The employee's hair or body parts other than hands, face, and neck could reasonably have become contaminated with beryllium.

(4) * * *

(i) Beryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with beryllium-contaminated personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body; and

* * * * *

(j) * * *

(1) * * *

(i) The employer must maintain all surfaces in beryllium work areas and regulated areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard; and

* * * * *

(2) * * *

(i) The employer must ensure that surfaces in beryllium work areas and regulated areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas or regulated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

* * * * *

(3) *Disposal and recycling.* For materials that contain beryllium in concentrations of 0.1 percent by weight or more or are contaminated with beryllium, the employer must ensure that:

(i) Materials designated for disposal are disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard; and

(ii) Materials designated for recycling are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or place in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard.

* * * * *

[FR Doc. 2018–09306 Filed 5–4–18; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

32 CFR Part 2004

[FDMS No. NARA–16–0006; Agency No. NARA–2018–032]

RIN 3095–AB79

National Industrial Security Program

AGENCY: National Archives and Records Administration (NARA).

ACTION: Final rule.

SUMMARY: The Information Security Oversight Office (ISOO) of the National Archives and Records Administration (NARA), is revising the National Industrial Security Program (NISP) Directive. The NISP safeguards classified information the Federal Government or foreign governments release to contractors, licensees, grantees, and certificate holders. This revision adds provisions incorporating executive branch insider threat policy and minimum standards, identifies the Office of the Director of National Intelligence (ODNI) and the Department of Homeland Security (DHS) as new cognizant security agencies (CSAs), and adds responsibilities for all CSAs and non-CSA departments and agencies (to reflect oversight functions that are already detailed for private sector entities in the National Industrial Security Program Operating Manual (NISPOM)). This revision also makes other administrative changes to be consistent with recent revisions to the NISPOM and with updated regulatory language and style.

DATES: This rule is effective on May 7, 2018.

ADDRESSES: National Archives and Records Administration; ATTN: External Policy Program, Suite 4100, 8601 Adelphi Road; College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT: For information about this regulation and the regulatory process, contact Kimberly Keravuori, External Policy Program Manager, by email at *regulation_comments@nara.gov,* or by telephone at 301.837.3151. For information about the NISP and the requirements in this regulation, contact Mark A. Bradley, Director, ISOO, by telephone at 202–357–5205.

SUPPLEMENTARY INFORMATION: We published proposed revisions to this rule in the **Federal Register** on January 11, 2017 (82 FR 3219) and received seven sets of public comments in response, from companies, industry representative organizations, and law firms. The vast majority of the comments were on 32 CFR 2004.32 and 2004.34, relating to national interest determinations (NIDs) made when an entity is under foreign ownership, control, or influence (FOCI) and the proposed mitigation method is a special security agreement. Overall, commenters strongly recommended that NIDs be eliminated, but, if not possible to do so, the commenters suggested ways in which to streamline the process and the regulatory provisions, including granting the Defense Security Service (DSS) authority to make NIDs concurrently with making eligibility determinations, establishing a presumption of approval if an entity otherwise has a favorable record, and making NIDs prior to contract awards.

We are not at this time able to eliminate NIDs because certain categories of classified information involve assessment of factors specific to that information. The regulation is also not drafted on the basis of what DSS may or may not do, as DSS is not one of the cognizant security agencies (CSAs) specifically named in Executive Order (E.O.) 12829. DSS has authority granted to it by the Department of Defense, one of the CSAs, and each CSA has equivalent authority under the NISP to make entity eligibility determinations and NIDs. We decline to create a presumption of approval because of the potential risk to national security, particularly with regard to certain categories of proscribed information. In addition, no agency has the capability to evaluate companies for a NID prior to any acquisition activity so as to include the NID in contract award documents.

Nonetheless, we have taken the comments and suggestions into consideration and made changes to further streamline the NID process and these regulatory sections in response to the public comments. We have established that the CSA (or DSS for the CSA, in the case of DoD determinations) makes the NID and does so concurrently with making the entity eligibility determination. In this manner, for several categories of classified information, the NID will take no longer than the entity eligibility determination. In cases in which the proscribed information does not require concurrence from a controlling agency, the entity's access may begin as soon as a positive determination is made. Now, only in cases in which the proscribed information requires concurrence from a controlling agency (RD, COMSEC, SCI), must the entity wait in order to have access to that information. We have revised the process to also allow an entity to begin accessing a category of proscribed information once the CSA informs the entity that the controlling agency concurs, even if other categories of proscribed information are pending concurrence. This allows entities to begin work and have access to at least part of the information at a faster rate.

In addition, we revised the regulation to allow an entity's access to SCI, RD, or COMSEC to remain in effect so long as the entity remains eligible for access to classified information and the contract or agreement imposing the requirement for access to those categories of proscribed information remains in effect, except under certain circumstances, and to remain in effect across contract renewals, new task orders, and SSA renewals (except under certain circumstances). Both of these revisions reduce the number of NIDs an entity must undergo and reduce the potential disruptions and burdens of previous NID frequency. We believe these regulations significantly streamline the NID process and reduce burdens on entities by: (1) Allowing the CSA to render NIDs for certain categories of information concurrently with eligibility determinations, (2) allowing access to information as NID concurrences are received rather than waiting for all concurrences, and (3) establishing a 30-day timeline for concurrence (this was included in the proposed rule).

We have coordinated and vetted the comments and resulting revisions through the CSAs listed in E. O. 12829, National Industrial Security Program (January 6, 1993 (58 FR 3479)), as amended by E.O. 13691 (February 13, 2015 (80 FR 9347)): Department of Defense, Department of Energy, Nuclear Regulatory Commission, Office of the Director of National Intelligence, and Department of Homeland Security. We have also coordinated this rule with the other executive branch agencies that are members of the National Industrial Security Program Policy Advisory Committee (NISPPAC) or that release classified information to contractors, licensees, grantees, or certificate holders, and with the industry members of the NISPPAC. These revisions do not change requirements for industry (which are contained in the NISPOM), but instead clarify agency responsibilities.

Background

The NISP is the Federal Government's single, integrated industrial security program. E.O. 12829 (amended in 1993) established the NISP to safeguard classified information in industry and

preserve the nation's economic and technological interests. The President issued E.O. 13691, Promoting Private Sector Cybersecurity Information Sharing (February 13, 2015 (80 FR 9347)), and E.O. 13708, Continuance or Reestablishment of Certain Federal Advisory Committees (September 30, 2015 (80 FR 60271)), which further amended E.O. 12829.

E.O. 12829, sec. 102(b), delegated oversight of the NISP to the Director of NARA's Information Security Oversight Office (ISOO). As part of ISOO's responsibilities under E.O. 12829, it is authorized to issue such directives as necessary to implement the E.O., which are binding on agencies. In 2006, ISOO issued, and periodically updates, this regulation, which functions as one of those directives.

This regulation establishes uniform standards throughout the Program, and helps agencies implement requirements in E.O. 12829, as amended (collectively referred to as ''E.O. 12829'').

This revision also establishes agency responsibilities for implementing the insider threat provisions of E.O. 13587, Structural Reforms to Improve the Security of Classified Networks and the Responsible Sharing and Safeguarding of Classified Information (October 7, 2011 (76 FR 63811)) within the NISP. However, the regulation does not stand alone; users should refer concurrently to the underlying executive orders for guidance.

Nothing in this regulation supersedes the authority of the Secretary of Energy or the Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011, *et seq.*); the authority of the Director of National Intelligence (or any intelligence community element) under the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458), the National Security Act of 1947 (50 U.S.C. 401, *et seq.*), as amended, and E.O. 12333 (December 4, 1981), as amended by E.O. 13355, Strengthened Management of the Intelligence Community (August 27, 2004) and E.O. 13470, Further Amendments to Executive Order 12333 (July 30, 2008); or the authority of the Secretary of Homeland Security, as the Executive Agent for the Classified National Security Information Program established under E.O. 13549, Classified National Security Information Program for State, Local, Tribal, and Private Sector Entities (August 18, 2010), or by E. O. 13284, Amendment of Executive Orders, and Other Actions, in Connection with the Establishment of the Department of Homeland Security, (January 23, 2003).

Regulatory Analysis

The Office of Management and Budget (OMB) has reviewed this proposed regulation.

Review Under Executive Orders 12866 and 13563

Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (September 30, 1993), and Executive Order 13563, Improving Regulation and Regulation Review, 76 FR 23821 (January 18, 2011), 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). This rule is not ''significant'' under Executive Order 12866, sec. 3(f), and is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. The Office of Management and Budget (OMB) has reviewed this regulation.

Review Under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*)

This review requires an agency to prepare an initial regulatory flexibility analysis and publish it when the agency publishes the proposed rule. This requirement does not apply if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities (5 U.S.C. 603). As required by the Regulatory Flexibility Act, we certify that this rulemaking will not have a significant impact on a substantial number of small entities because it applies only to Federal agencies. This regulation does not establish requirements for entities; those requirements are established in the NISPOM. This rule sets out coinciding requirements for agencies. However, agencies implementing this regulation will do so through contracts with businesses (as well as other agreements with entities) and thus it indirectly affects those entities. Agencies have been applying the requirements and procedures contained in the NISPOM (and, to a lesser extent, contained in this regulation) to entities for 20 years, with the exception of insider threat provisions added to the NISPOM in 2016, and the additions to this regulation do not substantially alter those requirements. Most of the provisions being added to this regulation have applied to entities through the NISPOM; we are simply incorporating the agency responsibilities for those requirements into the regulation. Other revisions to this regulation are primarily administrative, except the new insider threat requirements. The insider threat requirements make minor additions to training, oversight, information system security, and similar functions already being conducted by entities, and thus will not have a significant economic impact on a substantial number of small business entities.

Review Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.)

This rule contains information collection activities that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. We refer to the following OMB-approved DoD information collection in § 2004.34(b) and (c)(1) of this regulation: OMB control No. 0704–0194, SF 328/CF 328, Certificate Pertaining to Foreign Interests, approved through September 30, 2019. DoD published the information collection notice in the **Federal Register** in May 2015 (80 FR 27938, May 15, 2015) for public comment, and the notice of OMB review in the **Federal Register** in July 2016 (81 FR 47790, July 22, 2016), providing a second opportunity for public comment.

Review Under Executive Order 13132, Federalism, 64 FR 43255 (August 4, 1999)

Review under Executive Order 13132 requires that agencies review regulations for federalism effects on the institutional interest of states and local governments, and, if the effects are sufficiently substantial, prepare a Federal assessment to assist senior policy makers. This rule will not have any direct effects on State and local governments within the meaning of the Executive Order. Therefore, this rule does not include a federalism assessment.

Review Under Executive Order 13771

This final rule is not subject to the requirements of Executive Order 13771 because this final rule is related to agency organization, management, or personnel.

List of Subjects in 32 CFR Part 2004

Classified information, National Industrial Security Program.

■ For the reasons stated in the preamble, the National Archives and Records Administration amends 32 CFR chapter XX by revising part 2004 to read as follows:

PART 2004—NATIONAL INDUSTRIAL SECURITY PROGRAM (NISP)

Subpart A—Implementation and Oversight

Subpart B—Administration

Subpart C—Operations

Authority: Section 102(b)(1) of E.O. 12829 (January 6, 1993), as amended by E.O. 12885 (December 14, 1993), E.O. 13691 (February 12, 2015), and section 4 of E.O. 13708 (September 30, 2015).

Subpart A—Implementation and Oversight

§ 2004.1 Purpose and scope.

(a) This part sets out the National Industrial Security Program (''NISP'' or ''the Program'') governing the protection of agency classified information released to Federal contractors, licensees, grantees, and certificate holders. It establishes uniform standards throughout the Program, and helps agencies implement requirements in E.O. 12829, National Industrial Security Program, as amended by E.O. 12558 and E.O.13691 (collectively referred to as ''E.O. 12829''), E.O. 13691, Promoting Private Sector Cybersecurity Information Sharing, and E.O. 13587, Structural Reforms to Improve the Security of Classified Networks and the Responsible Sharing and Safeguarding of Classified Information. It applies to any executive branch agency that releases classified information to current, prospective, or former Federal contractors, licensees, grantees, or certificate holders. However, this part does not stand alone; users should refer concurrently to the underlying executive orders for guidance. ISOO maintains policy oversight over the NISP as established by E.O.12829.

(b) This part also does not apply to release of classified information pursuant to criminal proceedings. The Classified Information Procedures Act (CIPA) (18 U.S.C. Appendix 3) governs release of classified information in criminal proceedings.

(c) Nothing in this part supersedes the authority of the Secretary of Energy or the Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011, *et seq.*) (collectively referred to as ''the Atomic Energy Act''); the authority of the Director of National Intelligence (or any intelligence community element) under the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458), the National Security Act of 1947 as amended (50 U.S.C. 401, *et seq.*), and E.O. 12333 (December 4, 1981), as amended by E.O. 13355, Strengthened Management of the Intelligence Community (August 27, 2004) and E.O. 13470, Further Amendments to Executive Order 12333 (July 30, 2008) (collectively referred to as ''E.O. 12333''); or the authority of the Secretary of Homeland Security, as the Executive Agent for the Classified National Security Information Program established under E.O. 13549, Classified National Security Information Program for State, Local, Tribal, and Private Sector Entities (August 18, 2010), or as established by E.O. 13284, Amendment of Executive Orders, and Other Actions, in Connection with the Establishment of the Department of Homeland Security (January 23, 2003). In exercising these authorities, CSAs make every effort to facilitate reciprocity, avoid duplication of regulatory requirements, and facilitate uniform standards.

§ 2004.4 Definitions that apply to this part.

(a) *Access* is the ability or opportunity to gain knowledge of classified information.

(b) *Agency(ies)* are any ''Executive agency'' as defined in 5 U.S.C. 105; any ''Military department'' as defined in 5 U.S.C. 102; and any other entity within the executive branch that releases classified information to private sector entities. This includes component agencies under another agency or under a cross-agency oversight office (such as ODNI with CIA), which are also agencies for purposes of this regulation.

(c) *Classified Critical Infrastructure Protection Program (CCIPP)* is the DHS program that executes the classified infrastructure protection program designated by E.O. 13691, ''Promoting Private Sector Cybersecurity Information Sharing.'' The Government uses this program to share classified cybersecurity-related information with employees of private sector entities that own or operate critical infrastructure. Critical infrastructure refers to systems and assets, whether physical or virtual, so vital to the United States that incapacitating or destroying such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination thereof. These entities include banks and power plants, among others. The sectors of critical infrastructure are listed in Presidential Policy Directive 21, *Critical Infrastructure Security and Resilience* (February 12, 2013).

(d) *Classified Critical Infrastructure Protection Program (CCIPP) security point of contact (security POC)* is an official whom a CCIPP entity designates to maintain eligibility information about the entity and its cleared employees, and to report that information to DHS. The CCIPP security POC must be eligible for access to classified information.

(e) *Classified information* is information the Government designates as requiring protection against unauthorized disclosure in the interest of national security, pursuant to E.O. 13526, Classified National Security Information, or any predecessor order, and the Atomic Energy Act of 1954, as amended. Classified information includes national security information (NSI), restricted data (RD), and formerly restricted data (FRD), regardless of its physical form or characteristics (including tangible items other than documents).

(f) *Cognizance* is the area over which a CSA has operational oversight. Normally, a statute or executive order establishes a CSA's cognizance over certain types of information, programs, or non-CSA agencies, although CSAs may also have cognizance through an agreement with another CSA or non-CSA agency or an entity. A CSA may have cognizance over a particular type(s) of classified information based on specific authorities (such as those listed in § 2004.1(c)), and a CSA may have cognizance over certain agencies or cross-agency programs (such as DoD's cognizance over non-CSA agencies as the EA for NISP, or ODNI's oversight (if applicable) of all intelligence community elements within the executive branch). Entities fall under a CSA's cognizance when they enter or compete to enter contracts or agreements to access classified

information under the CSA's cognizance, including when they enter or compete to enter such contracts or agreements with a non-CSA agency or another entity under the CSA's cognizance.

(g) *Cognizant security agencies (CSAs)* are the agencies E.O. 12829, sec. 202, designates as having NISP implementation and security responsibilities for their own agencies (including component agencies) and any entities and non-CSA agencies under their cognizance. The CSAs are: Department of Defense (DoD); Department of Energy (DOE); Nuclear Regulatory Commission (NRC); Office of the Director of National Intelligence (ODNI); and Department of Homeland Security (DHS).

(h) *Cognizant security office (CSO)* is an organizational unit to which the head of a CSA delegates authority to administer industrial security services on behalf of the CSA.

(i) *Contracts or agreements* are any type of arrangement between an agency and an entity or an agency and another agency. They include, but are not limited to, contracts, sub-contracts, licenses, certificates, memoranda of understanding, inter-agency service agreements, other types of documents or arrangements setting out responsibilities, requirements, or terms agreed upon by the parties, programs, projects, and other legitimate U.S. or foreign government requirements. FOCI mitigation or negation measures, such as Voting Trust Agreements, that have the word ''agreement'' in their title are not included in the term ''agreements'' within this part.

(j) *Controlling agency* is an agency that owns or controls the following categories of proscribed information and thus has authority over access to or release of the information: NSA for communications security information (COMSEC); DOE for restricted data (RD); and ODNI for sensitive compartmented information (SCI).

(k) *Entity* is a generic and comprehensive term which may include sole proprietorships, partnerships, corporations, limited liability companies, societies, associations, institutions, contractors, licensees, grantees, certificate holders, and other organizations usually established and operating to carry out a commercial, industrial, educational, or other legitimate business, enterprise, or undertaking, or parts of these organizations. It may reference an entire organization, a prime contractor, parent organization, a branch or division, another type of sub-element, a sub-contractor, subsidiary, or other subordinate or connected entity (referred to as ''sub-entities'' when necessary to distinguish such entities from prime or parent entities), a specific location or facility, or the headquarters/official business location of the organization, depending upon the organization's business structure, the access needs involved, and the responsible CSA's procedures. The term ''entity'' as used in this part refers to the particular entity to which an agency might release, or is releasing, classified information, whether that entity is a parent or subordinate organization.

(l) *Entity eligibility determination* is an assessment by the CSA as to whether an entity is eligible for access to classified information of a certain level (and all lower levels). Eligibility determinations may be broad or limited to specific contracts, sponsoring agencies, or circumstances. A favorable determination results in eligibility to access classified information under the cognizance of the responsible CSA to the level approved. When the entity would be accessing categories of information such as RD or SCI for which the CSA for that information has set additional requirements, CSAs must also assess whether the entity is eligible for access to that category. Some CSAs refer to their favorable determinations as facility security clearances (FCL). A favorable entity eligibility determination does not convey authority to store classified information.

(m) *Foreign interest* is any foreign government, element of a foreign government, or representative of a foreign government; any form of business enterprise or legal entity organized, chartered, or incorporated under the laws of any country other than the United States or its territories; and any person who is not a United States citizen or national.

(n) *Government contracting activity (GCA)* is an agency component or subcomponent to which the agency head delegates broad authority regarding acquisition functions. A foreign government may also be a GCA.

(o) *Industrial security services* are those activities performed by a CSA to verify that an entity is protecting classified information. They include, but are not limited to, conducting oversight reviews, making eligibility determinations, and providing agency and entity guidance and training.

(p) *Insider(s)* are entity employees who are eligible to access classified information and may be authorized access to any U.S. Government or entity resource (such as personnel, facilities, information, equipment, networks, or systems).

(q) *Insider threat* is the likelihood, risk, or potential that an insider will use his or her authorized access, wittingly or unwittingly, to do harm to the national security of the United States. Insider threats may include harm to entity or program information to the extent that the information impacts the entity's or agency's obligations to protect classified information.

(r) *Insider threat response action(s)* are actions (such as investigations) an agency takes to ascertain whether an insider threat exists, and actions the agency takes to mitigate the threat. Agencies may conduct insider threat response actions through their counterintelligence (CI), security, law enforcement, or inspector general organizations, depending on the statutory authority and internal policies that govern the agency.

(s) *Insider threat program senior official (SO)* is the official an agency head or entity designates with responsibility to manage, account for, and oversee the agency's or entity's insider threat program, pursuant to the National Insider Threat Policy and Minimum Standards. An agency may have more than one insider threat program SO.

(t) *Key managers and officials (KMO)* are the senior management official (or authorized executive official under CCIPP), the entity's security officer (or security POC under CCIPP), the insider threat program senior official, and other entity employees whom the responsible CSA identifies as having authority, direct or indirect, to influence or decide matters affecting the entity's management or operations, its contracts requiring access to classified information, or national security interests. They may include individuals who hold majority ownership interest in the entity (in the form of stock or other ownership interests).

(u) *Proscribed information* is information that is classified as top secret (TS) information; communications security (COMSEC) information (excluding controlled cryptographic items when un-keyed or utilized with unclassified keys); restricted data (RD); special access program information (SAP); or sensitive compartmented information (SCI).

(v) *Security officer* is a U.S. citizen employee the entity designates to supervise and direct security measures implementing NISPOM (or equivalent; such as DOE Orders) requirements. Some CSAs refer to this position as a facility security officer (FSO). The security officer must complete security training specified by the responsible CSA, and must have and maintain an

employee eligibility determination level that is at least the same level as the entity's eligibility determination level.

(w) *Senior agency official for NISP (SAO for NISP)* is the official an agency head designates to direct and administer the agency's National Industrial Security Program.

(x) *Senior management official (SMO)* is the person in charge of an entity. Under the CCIPP, this is the authorized executive official with authority to sign the security agreement with DHS.

(y) *Sub-entity* is an entity's branch or division, another type of sub-element, a sub-contractor, subsidiary, or other subordinate or connected entity. Sub-entities fall under the definition of ''entity,'' but this part refers to them as sub-entities when necessary to distinguish such entities from prime contractor or parent entities. See definition of ''entity'' in paragraph (k) of this section for more context.

§ 2004.10 Responsibilities of the Director, Information Security Oversight Office (ISOO).

The Director, ISOO:

(a) Implements E.O. 12829, including ensuring that:

(1) The NISP operates as a single, integrated program across the executive branch of the Federal Government (*i.e.,* such that agencies that release classified information to entities adhere to NISP principles);

(2) A responsible CSA oversees each entity's NISP implementation in accordance with § 2004.22;

(3) All agencies that contract for classified work include the Security Requirements clause, 48 CFR 52.204–2, from the Federal Acquisition Regulation (FAR), or an equivalent clause, in contracts that require access to classified information;

(4) Those agencies for which the Department of Defense (DoD) serves as the CSA or provides industrial security services have agreements with DoD defining the Secretary of Defense's responsibilities on behalf of their agency;

(5) Each CSA issues directions to entities under their cognizance that are consistent with the NISPOM insider threat guidance;

(6) CSAs share with each other, as lawful and appropriate, relevant information about entity employees that indicates an insider threat; and

(7) CSAs conduct ongoing analysis and adjudication of adverse or relevant information about entity employees that indicates an insider threat.

(b) Raises an issue to the National Security Council (NSC) for resolution if the EA's NISPOM coordination process cannot reach a consensus on NISPOM security standards (see § 2004.20(d)).

§ 2004.11 CSA and agency implementing regulations, internal rules, or guidelines.

(a) Each CSA implements NISP practices in part through policies and guidelines that are consistent with this regulation, so that agencies for which it serves as the CSA are aware of appropriate security standards, engage in consistent practices with entities, and so that practices effectively protect classified information those entities receive (including foreign government information that the U.S. Government must protect in the interest of national security).

(b) Each CSA must also routinely review and update its NISP policies and guidelines and promptly issue revisions when needed (including when a change in national policy necessitates a change in agency NISP policies and guidelines).

(c) Non-CSA agencies may choose to augment CSA NISP policies or guidelines as long as the agency policies or guidelines are consistent with the CSA's policies or guidelines and this regulation.

§ 2004.12 ISOO review of agency NISP implementation.

(a) ISOO fulfills its oversight role based, in part, on information received from NISP Policy Advisory Committee (NISPPAC) members, from on-site reviews that ISOO conducts under the authority of E.O. 12829, and from any submitted complaints and suggestions. ISOO reports findings to the responsible CSA or agency.

(b) ISOO reviews agency policies and guidelines to ensure consistency with NISP policies and procedures. ISOO may conduct reviews during routine oversight visits, when a problem or potential problem comes to ISOO's attention, or after a change in national policy that impacts agency policies and guidelines. ISOO provides the responsible agency with findings from these reviews.

Subpart B—Administration

§ 2004.20 National Industrial Security Program Executive Agent and Operating Manual.

(a) The executive agent (EA) for NISP is the Secretary of Defense. The EA:

(1) Provides industrial security services for agencies that are not CSAs but that release classified information to entities. The EA provides industrial security services only through an agreement with the agency. Non-CSA agencies must enter an agreement with the EA and comply with EA industrial security service processes before releasing classified information to an entity;

(2) Provides services for other CSAs by agreement; and

(3) Issues and maintains the National Industrial Security Program Operating Manual (NISPOM) in consultation with all affected agencies and with the concurrence of the other CSAs.

(b) The NISPOM sets out the procedures and standards that entities must follow during all phases of the contracting process to safeguard any classified information an agency releases to an entity. The NISPOM requirements may apply to the entity directly (*i.e.,* through FAR clauses or other contract clauses referring entities to the NISPOM) or through equivalent contract clauses or requirements documents that are consistent with NISPOM requirements.

(c) The EA, in consultation with all affected agencies and with the concurrence of the other CSAs, develops the requirements, restrictions, and safeguards contained in the NISPOM. The EA uses security standards applicable to agencies as the basis for developing NISPOM entity standards to the extent practicable and reasonable.

(d) The EA also facilitates the NISPOM coordination process, which addresses issues raised by entities, agencies, ISOO, or the NISPPAC, including requests to create or change NISPOM security standards.

§ 2004.22 Agency responsibilities.

(a) *Agency categories and general areas of responsibility.* Federal agencies fall into three categories for the purpose of NISP responsibilities:

(1) *CSAs.* CSAs are responsible for carrying out NISP implementation within their agency, for providing NISP industrial security services on behalf of non-CSA agencies by agreement when authorized, and for overseeing NISP compliance by entities that access classified information under the CSA's cognizance. When the CSA has oversight responsibilities for a particular non-CSA agency or for an entity, the CSA also functions as the responsible CSA;

(2) *Non-CSA agencies.* Non-CSA agencies are responsible for entering agreements with a designated CSA for industrial security services, and are responsible for carrying out NISP implementation within their agency consistently with the agreement, the CSA's guidelines and procedures, and this regulation; or

(3) *Agencies that are components of another agency.* Component agencies do not have itemized responsibilities under this regulation and do not

independently need to enter agreements with a CSA, but they follow, and may have responsibilities under, implementing guidelines and procedures established by their CSA or non-CSA agency, or both.

(b) *Responsible CSA role.* (1) The responsible CSA is the CSA (or its delegated CSO) that provides NISP industrial security services on behalf of an agency, determines an entity's eligibility for access, and monitors and inspects an entity's NISP implementation.

(2) In general, the goal is to have one responsible CSA for each agency and for each entity, to minimize the burdens that can result from complying with differing CSA procedures and requirements.

(i) With regard to agencies, NISP accomplishes this goal by a combination of designated CSAs and agreements between agencies and CSAs.

(ii) With regard to entities, CSAs strive to reduce the number of responsible CSAs for a given entity as much as possible. To this end, when more than one CSA releases classified information to a given entity, those CSAs agree on which is the responsible CSA. However, due to certain unique agency authorities, there may be circumstances in which a given entity is under the oversight of more than one responsible CSA.

(3) Responsible CSA for agencies:

(i) In general, each CSA serves as the responsible CSA for classified information that it (or any of its component agencies) releases to entities, unless it enters an agreement otherwise with another CSA.

(ii) DoD serves as the responsible CSA for DHS with the exception of the CCIPP, based on an agreement between the two CSAs.

(iii) DoD serves as the responsible CSA on behalf of all non-CSA agencies, except CSA components, based on E.O. 12829 and its role as NISP EA.

(iv) ODNI serves as the responsible CSA for CIA.

(4) Responsible CSA for entities: When determining the responsible CSA for a given entity, the involved CSAs consider, at a minimum: retained authorities, the information's classification level, number of contracts requiring access to classified information, location, number of Government customers, volume of classified activity, safeguarding requirements, responsibility for entity employee eligibility determinations, and any special requirements.

(5) Responsible CSAs may delegate oversight responsibility to a cognizant security office (CSO) through CSA policy or by written delegation. The CSA must inform entities under its cognizance if it delegates responsibilities. For purposes of this rule, the term CSA also refers to the CSO.

(c) *CSA responsibilities.* (1) The CSA may perform GCA responsibilities as its own GCA.

(2) As CSA, the CSA performs or delegates the following responsibilities:

(i) Designates a CSA senior agency official (SAO) for NISP;

(ii) Identifies the insider threat program senior official (SO) to the Director, ISOO;

(iii) Shares insider threat information with other CSAs, as lawful and appropriate, including information that indicates an insider threat about entity employees eligible to access classified information;

(iv) Acts upon and shares—with security management, GCAs, insider threat program employees, and Government program and CI officials—any relevant entity-reported information about security or CI concerns, as appropriate;

(v) Submits reports to ISOO as required by this part; and

(vi) Develops, coordinates, and provides concurrence on changes to the NISPOM when requested by the EA.

(3) As a responsible CSA, the CSA also performs or delegates the following responsibilities:

(i) Determines whether an entity is eligible for access to classified information (see § 2004.32);

(ii) Allocates funds, ensures appropriate investigations are conducted, and determines entity employee eligibility for access to classified information (see § 2004.36);

(iii) Reviews and approves entity safeguarding measures, including making safeguarding capability determinations (see § 2004.38);

(iv) Conducts periodic security reviews of entity operations (see § 2004.26) to determine that entities: effectively protect classified information provided to them; and follow NISPOM (or equivalent) requirements;

(v) Provides and regularly updates guidance, training, training materials, and briefings to entities on:

(A) Entity implementation of NISPOM (or equivalent) requirements, including: responsibility for protecting classified information, requesting NISPOM interpretations, establishing training programs, and submitting required reports;

(B) Initial security briefings and other briefings required for special categories of information;

(C) Authorization measures for information systems processing classified information (except DHS) (see § 2004.40);

(D) Security training for security officers (or CCIPP POCs) and other employees whose official duties include performing NISP-related functions;

(E) Insider threat programs in accordance with the National Insider Threat Policy and Minimum Standards for Executive Branch Insider Threat Programs; and

(F) Other guidance and training as appropriate;

(vi) Establishes a mechanism for entities to submit requests for waivers to NISPOM (or equivalent) provisions;

(vii) Reviews, continuously analyzes, and adjudicates, as appropriate, reports from entities regarding events that:

(A) Impact the status of the entity's eligibility for access to classisfied information;

(B) Impact an employee's eligibility for access;

(C) May indicate an employee poses an insider threat;

(D) Affect proper safeguarding of classified information; or

(E) Indicate that classified information has been lost or compromised;

(viii) Verifies that reports offered in confidence and so marked by an entity may be withheld from public disclosure under applicable exemptions of the Freedom of Information Act (5 U.S.C. 552);

(ix) Requests any additional information needed from an entity about involved employees to determine continued eligibility for access to classified information when the entity reports loss, possible compromise, or unauthorized disclosure of classified information; and

(x) Posts hotline information on its website for entity access, or otherwise disseminates contact numbers to the entities for which the CSA is responsible.

(d) *Non-CSA agency head responsibilities.* The head of a non-CSA agency that is not a CSA component and that releases classified information to entities, performs the following responsibilities:

(1) Designates an SAO for the NISP;

(2) Identifies the insider threat program SO to ISOO to facilitate information sharing;

(3) Enters into an agreement with the EA (except agencies that are components of another agency or a cross-agency oversight office) to act as the responsible CSA on the agency's behalf (see paragraph (a)(1)(ii) of this section);

(4) Performs, or delegates in writing to a GCA, the following responsibilities:

(i) Provides appropriate education and training to agency personnel who implement the NISP;

(ii) Includes FAR security requirements clause 52.204–2, or equivalent (such as the DEAR clause 952.204–2), and a contract security classification specification (or equivalent guidance) into contracts and solicitations that require access to classified information (see § 2004.30); and

(iii) Reports to the appropriate CSA adverse information and insider threat activity pertaining to entity employees having access to classified information.

§ 2004.24 Insider threat program.

(a) Responsible CSAs oversee and analyze entity activity to ensure entities implement an insider threat program in accordance with the National Insider Threat Policy and Minimum Standards for Executive Branch Insider Threat Programs (via requirements in the NISPOM or its equivalent) and guidance from the CSA. CSA oversight responsibilities include, but are not limited to:

(1) Verifying that entities appoint insider threat program SOs;

(2) Requiring entities to monitor, report, and review insider threat program activities and response actions in accordance with the provisions set forth in the NISPOM (or equivalent);

(3) Providing entities with access to data relevant to insider threat program activities and applicable reporting requirements and procedures;

(4) Providing entities with a designated means to report insider threat-related activity; and

(5) Advising entities on appropriate insider threat training for entity employees eligible for access to classified information.

(b) CSAs share with other CSAs any insider threat information reported to them by entities, as lawful and appropriate.

§ 2004.26 Reviews of entity NISP implementation.

(a) The responsible CSA conducts recurring oversight reviews of entities' NISP security programs to verify that the entity is protecting classified information and is implementing the provisions of the NISPOM (or equivalent). The CSA determines the scope and frequency of reviews. The CSA generally notifies entities when a review will take place, but may also conduct unannounced reviews at its discretion.

(b) CSAs make every effort to avoid unnecessarily intruding into entity employee personal effects during the reviews.

(c) A CSA may, on entity premises, physically examine the interior spaces of containers not authorized to store classified information in the presence of the entity's representative.

(d) As part of a security review, the CSA:

(1) Verifies that the entity limits entity employees with access to classified information to the minimum number necessary to perform on contracts requiring access to classified information.

(2) Validates that the entity has not provided its employees unauthorized access to classified information;

(3) Reviews the entity's self-inspection program and evaluates and records the entity's remedial actions; and

(4) Verifies that the GCA approved any public release of information pertaining to a contract requiring access to classified information.

(e) As a result of findings during the security review, the CSA may, as appropriate, notify:

(1) GCAs if there are unfavorable results from the review; and

(2) A prime entity if the CSA discovers unsatisfactory security conditions pertaining to a sub-entity.

(f) The CSA maintains a record of reviews it conducts and the results. Based on review results, the responsible CSA determines whether an entity's eligibility for access to classified information may continue. See § 2004.32(g).

§ 2004.28 Cost reports.

(a) Agencies must annually report to the Director, ISOO, on their NISP implementation costs for the previous year.

(b) CSAs must annually collect information on NISP implementation costs incurred by entities under their cognizance and submit a report to the Director, ISOO.

Subpart C—Operations

§ 2004.30 Security classification requirements and guidance.

(a) *Contract or agreement and solicition requirements.* (1) The GCA must incorporate FAR clause 52.204–2, Security Requirements (or equivalent set of security requirements), into contracts or agreements and solicitations requiring access to classified information.

(2) The GCA must also include a contract security classification specification (or equivalent guidance) with each contract or agreement and solicitation that requires access to classified information. The contract security classification specification (or equivalent guidance) must identify the specific elements of classified information involved in each phase of the contract or agreement life-cycle, such as:

(i) Level of classification;

(ii) Where the entity will access or store the classified information, and any requirements or limitations on transmitting classified information outside the entity;

(iii) Any special accesses;

(iv) Any classification guides or other guidance the entity needs to perform during that phase of the contract or agreement;

(v) Any authorization to disclose information about the contract or agreement requiring access to classified information; and

(vi) GCA personnel responsible for interpreting and applying the contract security specifications (or equivalent guidance).

(3) The GCA revises the contract security classification specification (or equivalent guidance) throughout the contract or agreement life-cycle as security requirements change.

(b) *Guidance.* Classification guidance is the exclusive responsibility of the GCA. The GCA prepares classification guidance in accordance with 32 CFR 2001.15, and provides appropriate security classification and declassification guidance to entities.

(c) *Requests for clarification and classification challenges.* (1) The GCA responds to entity requests for clarification and classification challenges.

(2) The responsible CSA assists entities to obtain appropriate classification guidance from the GCA, and to obtain a classification challenge response from the GCA.

(d) *Instructions upon contract or agreement completion or termination.* (1) The GCA provides instructions to the entity for returning or disposing of classified information upon contract or agreement completion or termination, or when an entity no longer has a legitimate need to retain or possess classified information.

(2) The GCA also determines whether the entity may retain classified information for particular purposes after the contract or agreement terminates, and if so, provides written authorization to the entity along with any instructions or limitations (such as which information, for how long, etc).

§ 2004.32 Determining entity eligibility for access to classified information.

(a) *Eligibility determinations.* (1) The responsible CSA determines whether an

entity is eligible for access to classified information. An entity may not have access to classified information until the responsible CSA determines that it meets all the requirements in this section. In general, the entity must be eligible to access classified information at the appropriate level before the CSA may consider any of the entity's subsidiaries, sub-contractors, or other sub-entities for eligibility. However, when the subsidiary will perform all classified work, the CSA may instead exclude the parent entity from access to classified information rather than determining its eligibility. In either case, the CSA must consider all information relevant to assessing whether the entity's access poses an unacceptable risk to national security interests.

(2) A favorable access eligibility determination is not the same as a safeguarding capability determination. Entities may access classified information with a favorable eligibility determination, but may possess classified information only if the CSA determines both access eligibility and safeguarding capability, based on the GCA's requirement in the contract security classification specification (or equivalent).

(3) If an entity has an existing eligibility determination, a CSA will not duplicate eligibility determination processes performed by another CSA. If a CSA cannot acknowledge an entity eligibility determination to another CSA, that entity may be subject to duplicate processing.

(4) Each CSA maintains a record of its entities' eligibility determinations (or critical infrastructure entity eligibility status under the CCIPP, for DHS) and responds to inquiries from GCAs or entities, as appropriate and to the extent authorized by law, regarding the eligibility status of entities under their cognizance.

(b) *Process.* (1) The responsible CSA provides guidance to entities on the eligibility determination process and on how to maintain eligibility throughout the period of the agreement or as long as an entity continues to need access to classified information in connection with a legitimate U.S. or foreign government requirement.

(2) The CSA coordinates with appropriate authorities to determine whether an entity meets the eligibility criteria in paragraph (e) of this section. This includes coordinating with appropriate U.S. Government regulatory authorities to determine entity compliance with laws and regulations.

(3) An entity cannot apply for its own eligibility determination. A GCA or an eligible entity must sponsor the entity to the responsible CSA for an eligibility determination. The GCA or eligible entity may sponsor an entity at any point during the contracting or agreement life-cycle at which the entity must have access to classified information to participate (including the solicitation or competition phase). An entity with limited eligibility granted under paragraph (f) of this section may sponsor a sub-entity for a limited eligibility determination for the same contract, agreement, or circumstance so long as the sponsoring entity is not under FOCI (see § 2004.34(i)).

(4) The GCA must include enough lead time in each phase of the acquisition or agreement cycle to accomplish all required security actions. Required security actions include any eligibility determination necessary for an entity to participate in that phase of the cycle. The GCA may award a contract or agreement before the CSA completes the entity eligibility determination. However, in such cases, the entity may not begin performance on portions of the contract or agreement that require access to classified information until the CSA makes a favorable entity eligibility determination.

(5) When a CSA is unable to make an eligibility determination in sufficient time to qualify an entity to participate in the particular procurement action or phase that gave rise to the GCA request (this includes both solicitation and performance phases), the GCA may request that the CSA continue the determination process to qualify the entity for future classified work for any GCA, provided that the processing delay was not due to the entity's lack of cooperation. Once the CSA determines that an entity is eligible for access to classified information, but a GCA does not award a contract or agreement requiring access to classified information to the entity, or the entity's eligibility status changes, the CSA terminates the entity eligibility determination in accordance with paragraph (g) of this section.

(c) *Coverage.* (1) A favorable eligibility determination allows an entity to access classified information at the determined eligibility level, or lower.

(2) The CSA must ensure that all entities needing access to classified information as part of a legitimate U.S. or foreign government requirement have or receive a favorable eligibility determination before accessing classified information. This includes both prime or parent entities and sub-entities, even in cases in which an entity intends to have the classified work performed only by sub-entities. A prime or parent entity must have a favorable eligibility determination at the same classification level or higher than its sub-entity(ies), unless the CSA determined that the parent entity could be effectively excluded from access (see paragraph (a)(1) of this section).

(3) If a parent and sub-entity need to share classified information with each other, the CSA must validate that both the parent and the sub-entity have favorable eligibility determinations at the level required for the classified information prior to sharing the information.

(d) *DHS Classified Critical Infrastructure Protection Program (CCIPP).* DHS shares classified cybersecurity information with certain employees of entities under the Classified Critical Infrastructure Protection Program (CCIPP). The CCIPP applies only to entities that do not need to store classified information, have no other contracts or agreements already requiring access to classified information, and are not already determined eligible for access to classified information. DHS establishes and implements procedures consistent with the NISP to determine CCIPP entity eligibility for access to classified information.

(e) *Eligibility criteria.* An entity must meet the following requirements to be eligible to access classified information:

(1) It must need to access classified information as part of a legitimate U.S. Government or foreign government requirement, and access must be consistent with U.S. national security interests as determined by the CSA;

(2) It must be organized and existing under the laws of any of the 50 States, the District of Columbia, or an organized U.S. territory (Guam, Commonwealth of the Northern Marianas Islands, Commonwealth of Puerto Rico, and the U.S. Virgin Islands); or an American Indian or Alaska native tribe formally acknowledged by the Assistant Secretary—Indian Affairs, of the U.S. Department of the Interior;

(3) It must be located in the United States or its territorial areas;

(4) It must have a record of compliance with pertinent laws, regulations, and contracts (or other relevant agreements);

(5) Its KMOs must each have and maintain eligibility for access to classified information that is at least the same level as the entity eligibility level;

(6) It and all of its KMOs must not be excluded by a Federal agency, contract review board, or other authorized official from participating in Federal contracts or agreements;

(7) It must meet all requirements the CSA or the authorizing law, regulation, or Government-wide policy establishes for access to the type of classified information or program involved; and

(8) If the CSA determines the entity is under foreign ownership, control, or influence (FOCI), the responsible CSA must:

(i) Agree that sufficient security measures are in place to mitigate or negate risk to national security interests due to the FOCI (see § 2004.34);

(ii) Determine that it is appropriate to grant eligibility for a single, narrowly defined purpose (see § 2004.34(i)); or

(iii) Determine that the entity is not eligible to access classified information.

(9) DoD and DOE cannot award a contract involving access to proscribed information to an entity effectively owned or controlled by a foreign government unless the Secretary of the agency first issues a waiver (see 10 U.S.C. 2536). A waiver is not required if the CSA determines the entity is eligible and it agrees to establish a voting trust agreement (VTA) or proxy agreement (PA) (see § 2004.34(f)) because both VTAs and PAs effectively negate foreign government control.

(f) *Limited entity eligibility determination.* CSAs may choose to allow GCAs to request limited entity eligibility determinations (this is not the same as limited entity eligibility in situations involving FOCI when the FOCI is not mitigated or negated; for more information on limited entity eligibility in such FOCI cases, see § 2004.34(i)). If a CSA permits GCAs to request a limited entity eligibility determination, it must set out parameters within its implementing policies that are consistent with the following requirements:

(1) The GCA, or an entity with limited eligibility, must first request a limited entity eligibility determination from the CSA for the relevant entity and provide justification for limiting eligibility in that case;

(2) Limited entity eligibility is specific to the requesting GCA's classified information, and to a single, narrowly defined contract, agreement, or circumstance;

(3) The entity must otherwise meet the requirements for entity eligibility set out in this part;

(4) The CSA documents the requirements of each limited entity eligibility determination it makes, including the scope of, and any limitations on, access to classified information;

(5) The CSA verifies limited entity eligibility determinations only to the requesting GCA or entity. In the case of multiple limited entity eligibility determinations for a single entity, the CSA verifies each one separately only to its requestor; and

(6) CSAs administratively terminate the limited entity eligibility when there is no longer a need for access to the classified information for which the CSA approved the limited entity eligibility.

(g) *Terminating or revoking eligibility.* (1) The responsible CSA terminates the entity's eligible status when the entity no longer has a need for access to classified information.

(2) The responsible CSA revokes the entity's eligible status if the entity is unable or unwilling to protect classified information.

(3) The CSA coordinates with the GCA(s) to take interim measures, as necessary, toward either termination or revocation.

§ 2004.34 Foreign ownership, control, or influence (FOCI).

(a) *FOCI determination.* A U.S. entity is under foreign ownership, control, or influence (FOCI) when:

(1) A foreign interest has the power to direct or decide matters affecting the entity's management or operations in a manner that could:

(i) Result in unauthorized access to classified information; or

(ii) Adversely affect performance of a contract or agreement requiring access to classified information; and

(2) The foreign interest exercises that power:

(i) Directly or indirectly;

(ii) Through ownership of the U.S. entity's securities, by contractual arrangements, or other similar means;

(iii) By the ability to control or influence the election or appointment of one or more members to the entity's governing board (*e.g.,* board of directors, board of managers, board of trustees) or its equivalent; or

(iv) Prospectively (*i.e.,* is not currently exercising the power, but could).

(b) *CSA guidance.* The CSA establishes guidance for entities on filling out and submitting a Standard Form (SF) 328, Certificate Pertaining to Foreign Interests (OMB Control No. 0704–0194), and on reporting changes in circumstances that might result in a determination that the entity is under FOCI or is no longer under FOCI. The CSA also advises entities on the Government appeal channels for disputing CSA FOCI determinations.

(c) *FOCI factors.* To determine whether an entity is under FOCI, the CSA analyzes available information to determine the existence, nature, and source of FOCI. The CSA:

(1) Considers information the entity or its parent provides on the SF 328/CF 328 (OMB Control No. 0704–0194), and any other relevant information; and

(2) Considers in the aggregate the following factors about the entity:

(i) Record of espionage against U.S. targets, either economic or Government;

(ii) Record of enforcement actions against the entity for transferring technology without authorization;

(iii) Record of compliance with pertinent U.S. laws, regulations, and contracts or agreements;

(iv) Type and sensitivity of the information the entity would access;

(v) Source, nature, and extent of FOCI, including whether foreign interests hold a majority or minority position in the entity, taking into consideration the immediate, intermediate, and ultimate parent entities;

(vi) Nature of any relevant bilateral and multilateral security and information exchange agreements;

(vii) Ownership or control, in whole or in part, by a foreign government; and

(viii) Any other factor that indicates or demonstrates foreign interest capability to control or influence the entity's operations or management.

(d) *Entity access while under FOCI.* (1) If the CSA is determining whether an entity is eligible to access classified information and finds that the entity is under FOCI, the CSA must consider the entity ineligible for access to classified information. The CSA and the entity may then attempt to negotiate FOCI mitigation or negation measures sufficient to permit a favorable eligibility determination.

(2) The CSA may not determine that the entity is eligible to access classified information until the entity has put into place appropriate security measures to negate or mitigate FOCI or is otherwise no longer under FOCI. If the degree of FOCI is such that no mitigation or negation efforts will be sufficient, or access to classified information would be inconsistent with national security interests, then the CSA will determine the entity ineligible for access to classified information.

(3) If an entity comes under FOCI, the CSA may allow the existing eligibility status to continue while the CSA and the entity negotiate acceptable FOCI mitigation or negation measures, as long as there is no indication that classified information is at risk. If the entity does not actively negotiate mitigation or negation measures in good faith, or there are no appropriate measures that will remove the possibility of unauthorized access to classified information or adverse effect on the entity's performance of contracts or

agreements involving classified information, the CSA will take steps, in coordination with the GCA, to terminate eligibility.

(e) *FOCI and entities under the CCIPP.* DHS may sponsor, as part of the CCIPP, a U.S. entity that is under FOCI, under the following circumstances:

(1) The Secretary of DHS proposes appropriate FOCI risk mitigation or negation measures (see paragraph (f) of this section) to the other CSAs and ensures the anticipated release of classified information:

(i) Is authorized for release to the country involved;

(ii) Does not include information classified under the Atomic Energy Act; and

(iii) Does not impede or interfere with the entity's ability to manage and comply with regulatory requirements imposed by other Federal agencies, such as the State Department's International Traffic in Arms Regulation.

(2) If the CSAs agree the mitigation or negation measures are sufficient, DHS may proceed to enter a CCIPP information sharing agreement with the entity. If one or more CSAs disagree, the Secretary of DHS may seek a decision from the Assistant to the President for National Security Affairs before entering a CCIPP information sharing agreement with the entity.

(f) *Mitigation or negation measures to address FOCI.* (1) The CSA-approved mitigation or negation measures must assure that the entity can offset FOCI by effectively denying unauthorized people or entities access to classified information and preventing the foreign interest from adversely impacting the entity's performance on contracts or agreements requiring access to classified information.

(2) Any mitigation or negation measures the CSA approves for an entity must not impede or interfere with the entity's ability to manage and comply with regulatory requirements imposed by other Federal agencies (such as Department of State's International Traffic in Arms Regulation).

(3) If the CSA approves a FOCI mitigation or negation measure for an entity, it may agree that the measure, or particular portions of it, may apply to all of the present and future sub-entities within the entity's organization.

(4) Mitigation or negation measures are different for ownership versus control or influence.

(5) Methods to mitigate foreign control or influence (unrelated to ownership) may include:

(i) Assigning specific oversight duties and responsibilities to independent board members;

(ii) Formulating special executive-level security committees to consider and oversee matters that affect entity performance on contracts or agreements requiring access to classified information;

(iii) Modifying or terminating loan agreements, contracts, agreements, and other understandings with foreign interests;

(iv) Diversifying or reducing foreign-source income;

(v) Demonstrating financial viability independent of foreign interests;

(vi) Eliminating or resolving problem debt;

(vii) Separating, physically or organizationally, the entity component performing on contracts or agreements requiring access to classified information;

(viii) Adopting special board resolutions;

(ix) A combination of these methods, as determined by the CSA; or

(x) Other actions that effectively negate or mitigate foreign control or influence.

(6) Methods to mitigate or negate foreign ownership include:

(i) *Board resolutions.* The CSA and the entity may agree to a board resolution when a foreign interest does not own voting interests sufficient to elect, or is otherwise not entitled to representation on, the entity's governing board. The resolution must identify the foreign shareholders and their representatives (if any), note the extent of foreign ownership, certify that the foreign shareholders and their representatives will not require, will not have, and can be effectively excluded from, access to all classified information, and certify that the entity will not permit the foreign shareholders and their representatives to occupy positions that might enable them to influence the entity's policies and practices, affecting its performance on contracts or agreements requiring access to classified information.

(ii) *Security control agreements (SCAs).* The CSA and the entity may agree to use an SCA when a foreign interest does not effectively own or control an entity (*i.e.,* the entity is under U.S. control), but the foreign interest is entitled to representation on the entity's governing board. At least one cleared U.S. citizen must serve as an outside director on the entity's governing board.

(iii) *Special security agreements (SSAs).* The CSA and the entity may agree to use an SSA when a foreign interest effectively owns or controls an entity. The SSA preserves the foreign owner's right to be represented on the entity's board or governing body with a direct voice in the entity's business management, while denying the foreign owner majority representation and unauthorized access to classified information. When a GCA requires an entity to have access to proscribed information, and the CSA proposes an SSA as the mitigation measure, the CSA makes a national interest determination (NID) as part of determining an entity's eligibility for access. See paragraph (h) of this section for more information on NIDs.

(iv) *Voting trust agreements (VTAs) or proxy agreements (PAs).* The CSA and the entity may agree to use one of these measures when a foreign interest effectively owns or controls an entity. The VTA and PA are arrangements that vest the voting rights of the foreign-owned stock in cleared U.S. citizens approved by the CSA. Under the VTA, the foreign owner transfers legal title in the entity to the trustees approved by the CSA. Under the PA, the foreign owner conveys their voting rights to proxy holders approved by the CSA. The entity must be organized, structured, and financed to be capable of operating as a viable business entity independently from the foreign owner. Both VTAs and PAs can effectively negate foreign ownership and control; therefore, neither imposes any restrictions on the entity's eligibility to have access to classified information or to compete for contracts or agreements requiring access to classified information, including those involving proscribed information. Both VTAs and PAs can also effectively negate foreign government control.

(v) *Combinations of the measures in paragraphs (f)(6)(i) through (iv) of this section or other similar measures that effectively mitigate or negate the risks involved with foreign ownership.* CSAs must identify combination agreements in a way that distinguishes them from other agreements (*e.g.,* a combination SSA-proxy agreement cannot be identified as either an SSA or a proxy agreement beause those names would not distinguish the combination agreement from either of the other types). CSAs must also coordinate terms in combination agreements with the controlling agency prior to releasing proscribed information.

(g) *Standards for FOCI mitigation or negation measures.* The CSA must include the following requirements as part of any FOCI mitigation or negation measures, to ensure that entities implement necessary security and governing controls:

(1) Annual certification and annual compliance reports by the entity's governing board and the KMOs;

(2) The U.S. Government remedies in case the entity is not adequately protecting classified information or not adhering to the provisions of the mitigation or negation measure;

(3) Supplements to FOCI mitigation or negation measures as the CSA deems necessary. In addition to the standard FOCI mitigation or negation measure's requirements, the CSA may require more procedures via a supplement, based upon the circumstances of an entity's operations. The CSA may place these requirements in supplements to the FOCI mitigation or negation measure to allow flexibility as circumstances change without having to renegotiate the entire measure. When making use of supplements, the CSA does not consider the FOCI mitigation measure final until it approves the required supplements (*e.g.,* technology control plan, electronic communication plan); and

(4) For agreements to mitigate or negate ownership (PAs, VTAs, SSAs, and SCAs), the following additional requirements apply:

(i) *FOCI oversight.* The CSA verifies that the entity establishes an oversight body consisting of trustees, proxy holders or outside directors, as applicable, and those officers or directors whom the CSA determines are eligible for access to classified information (see § 2004.36). The entity's security officer is the principal advisor to the oversight body and attends their meetings. The oversight body:

(A) Maintains policies and procedures to safeguard classified information in the entity's possession with no adverse impact on performance of contracts or agreements requiring access to classified information; and

(B) Verifies the entity is complying with the FOCI mitigation or negation measure and related documents, contract security requirements or equivalent, and the NISP;

(ii) *Qualifications of trustees, proxy holders, and outside directors.* The CSA determines eligibility for access to classified information for trustees, proxy holders, and outside directors at the classification level of the entity's eligibility determination. Trustees, proxy holders, and outside directors must meet the following criteria:

(A) Be a U.S. citizen residing in the United States who can exercise management prerogatives relating to their position in a way that ensures that the foreign owner can be effectively insulated from the entity or effectively separated from the entity's classified work;

(B) Be completely disinterested individuals with no prior involvement with the entity, the entities with which it is affiliated, or the foreign owner and its affiliates. Individuals who are serving as trustees, proxy holders, or outside directors as part of a mitigation measure for the entity are not considered to have prior involvement solely by performing that role; and

(C) Be involved in no other circumstances that may affect an individual's ability to serve effectively, such as the number of boards on which the individual serves or the length of time serving on any other boards;

(iii) *Annual meeting.* The CSA meets at least annually with the oversight body to review the purpose and effectiveness of the FOCI mitigation or negation agreement; establish a common understanding of the operating requirements and their implementation; and provide guidance on matters related to FOCI mitigation and industrial security. These meetings include a CSA review of:

(A) Compliance with the approved FOCI mitigation or negation measure;

(B) Problems regarding practical implementation of the mitigation or negation measure; and

(C) Security controls, practices, or procedures and whether they warrant adjustment; and

(iv) *Annual certification.* The CSA reviews the entity's annual report; addresses, and resolves issues identified in the report; and documents the results of this review and any follow-up actions.

(h) *National interest determination (NID)*—(1) *Requirement for a NID.* (i) The CSA must determine whether allowing an entity access to proscribed information under an SSA is consistent with national security interests of the United States as part of making an entity eligibility determination in cases in which:

(A) The GCA requires an entity to have access to proscribed information;

(B) The entity is under FOCI; and

(C) The CSA proposes an SSA to mitigate the FOCI.

(ii) This determination is called a national interest determination (NID). A favorable NID confirms that an entity's access to the proscribed information under an SSA is consistent with national security interests. If the CSA is unable to render a favorable NID, it must consider other FOCI mitigation measures instead of an SSA or reassess the entity's eligibility for access to classified information.

(2) *NID process.* (i) The CSA makes the NID for any categories of proscribed information for which the entity requires access.

(ii) In cases in which any category of the proscribed information is controlled by another agency (ODNI for SCI, DOE for RD, NSA for COMSEC), the CSA asks that controlling agency to concur on the NID for that category of information.

(iii) The CSA informs the GCA and the entity when the NID is complete. In cases involving SCI, RD, or COMSEC, the CSA also informs the GCA and the entity when a controlling agency concurs or non-concurs on that agency's category of proscribed information. The entity may begin accessing a category of proscribed information once the CSA informs the GCA and the entity that the controlling agency concurs, even if other categories of proscribed information are pending concurrence.

(iv) An entity's access to SCI, RD, or COMSEC remains in effect so long as the entity remains eligible for access to classified information and the contract or agreement (or program or project) which imposes the requirement for access to those categories of proscribed information remains in effect, except under the following circumstances:

(A) The CSA, GCA, or controlling agency becomes aware of adverse information that impacts the entity eligibility determination;

(B) The CSA's threat assessment pertaining to the entity indicates a risk to one of the categories of proscribed information;

(C) The CSA becomes aware of any material change regarding the source, nature, and extent of FOCI; or

(D) The entity's record of NISP compliance, based on CSA reviews in accordance with § 2004.26, becomes less than satisfactory.

(v) Under any of these circumstances, the CSA determines whether an entity may continue being eligible for access to classified information, it must change the FOCI mitigation measure in order to remain eligible, or the CSA must terminate or revoke access.

(3) *Process for concurring or non-concurring on a NID.* (i) Each controlling agency tells the CSAs what information the controlling agency requires to consider a NID. ODNI identifies the information it requires to assess a NID for access to SCI, DOE identifies the information it requires to assess a NID for access to RD, and NSA identifies the information it requires to assess a NID for access to COMSEC.

(ii) The CSA requests from the GCA justification for access, a description of the proscribed information involved, and other information the controlling agency requires to concur or non-concur on the NID.

(iii) The CSA requests concurrence on the NID from the controlling agency for the relevant category of proscribed information (ODNI for SCI, DOE for RD,

NSA for COMSEC), and provides the information that controlling agency identified.

(iv) The relevant controlling agency (ODNI for SCI, DOE for RD, NSA for COMSEC) responds in writing to the CSA's request for concurrence.

(A) The controlling agency may concur with the NID for access under a particular contract or agreement, access under a program or project, or for all future access to the same category of proscribed information.

(B) If the relevant controlling agency does not concur with the NID, the controlling agency informs the CSA in writing, citing the reasons why it does not concur. The CSA notifies the applicable GCA and, in coordination with the GCA, then notifies the entity. The entity cannot have access to the category of proscribed information under the control of that agency (*i.e.,* if ODNI does not concur, the entity may not have access to SCI; if DOE does not concur, the entity may not have access to RD; and if NSA does not concur, the entity may not have access to COMSEC). The CSA, in consultation with the applicable GCA, must decide whether the reason the controlling agency did not concur otherwise affects the entity's eligibility for access to classified information (see § 2004.32(g)), or requires changing the FOCI mitigation measure (see paragraph (f) of this section).

(v) When an entity is eligible for access to classified information that includes a favorable NID for SCI, RD, or COMSEC, the CSA does not have to request a new NID concurrence for the same entity if the access requirements for the relevant category of proscribed information and terms remain unchanged for:

(A) Renewing the contract or agreement;

(B) New task orders issued under the contract or agreement;

(C) A new contract or agreement that contains the same provisions as the previous one (this usually applies when the contract or agreement is for a program or project); or

(D) Renewing the SSA.

(vi) When making the decision whether or not to concur with a NID for proscribed information under its control, the controlling agency will not duplicate work already performed by the GCA during the contract award process or by the CSA when determining entity eligibility for access to classified information.

(4) *Timing for concurrence process.* (i) The CSA requests NID concurrence from the controlling agency as soon as the CSA has made a NID, if the entity needs access to SCI, RD, or COMSEC.

(ii) The controlling agency provides a final, written concurrence or non-concurrence to the CSA within 30 days after receiving the request for concurrence from the CSA.

(iii) In cases when a controlling agency requires clarification or additional information from the CSA, the controlling agency responds to the CSA within 30 days to request clarification or additional information as needed, and to coordinate a plan and timeline for concurring or non-concurring. The controlling agency must provide written updates to the CSA every 30 days until it concurs or non-concurs. In turn, the CSA provides the GCA and the entity with updates every 30 days.

(i) *Limited eligibility determinations (for entities under FOCI without mitigation or negation).* (1) In exceptional circumstances when an entity is under FOCI, the CSA may decide that limited eligibility for access to classified information is appropriate when the entity is unable or unwilling to implement FOCI mitigation or negation measures (this is not the same as limited eligibility in other circumstances; for more information on limited eligibility in other cases, see § 2004.32(f)).

(2) The GCA first decides whether to request a limited eligibility determination for the entity and must articulate a compelling need for it to the CSA that is in accordance with U.S. national security interests. The GCA must verify to the CSA that access to classified information is essential to contract or agreement performance, and accept the risk inherent in not mitigating or negating the FOCI. See § 2004.32(b)(3).

(3) The CSA may grant a limited eligibility determination if the GCA requests and the entity meets all other eligibility criteria in § 2004.32(e).

(4) A foreign government may sponsor a U.S. sub-entity of a foreign entity for limited eligibility when the foreign government desires to award a contract or agreement to the U.S. sub-entity that involves access to classified information for which the foreign government is the original classification authority (*i.e.,* foreign government information), and there is no other need for the U.S. sub-entity to have access to classified information.

(5) Limited eligibility determinations are specific to the classified information of the requesting GCA or foreign government, and specific to a single, narrowly defined contract, agreement, or circumstance of that GCA or foreign government.

(6) The access limitations of a favorable limited eligibility determination apply to all of the entity's employees, regardless of citizenship.

(7) A limited eligibility determination is not an option for entities that require access to proscribed information when a foreign government has ownership or control over the entity. See § 2004.32(e)(9).

(8) The CSA administratively terminates the entity's limited eligibility when there is no longer a need for access to the classified information for which the CSA made the favorable limited eligibility determination. Terminating one limited eligibility status does not impact other ones the entity may have.

§ 2004.36 Determining entity employee eligibility for access to classified information.

(a) *Making employee eligibility determinations.* (1) The responsible CSA:

(i) Determines whether entity employees meet the criteria established in the Security Executive Agent Directive (SEAD) 4, National Security Adjudicative Guidelines (December 10, 2016). Entity employees must have a legitimate requirement (*i.e.,* need to know) for access to classified information in the performance of assigned duties and eligibility must be clearly consistent with the interest of the national security.

(ii) Notifies entities of its determinations of employee eligibility for access to classified information.

(iii) Terminates eligibility status when there is no longer a need for access to classified information by entity employees.

(2) The responsible CSA maintains:

(i) SF 312s, Classified Information Nondisclosure Agreements, or other approved nondisclosure agreements, executed by entity employees, as prescribed by ODNI in accordance with 32 CFR 2001.80 and E.O. 13526; and

(ii) Records of its entity employee eligibility determinations, suspensions, and revocations.

(3) CSAs ensure that entities limit the number of employees with access to classified information to the minimum number necessary to work on contracts or agreements requiring access to classified information.

(4) The CSA determines the need for event-driven reinvestigations for entity employees.

(5) CSAs use the Federal Investigative Standards (FIS) issued jointly by the Suitability and Security Executive Agents.

(6) The CSA provides guidance to entities on:

(i) Requesting employee eligibility determinations, to include guidance for submitting fingerprints; and

(ii) Granting employee access to classified information when the employee has had a break in access or a break in employment.

(7) If the CSA receives adverse information about an eligible entity employee, the CSA should consider and possibly investigate, as authorized, to determine whether the employee's eligibility to access classified information remains clearly consistent with the interests of national security. If the CSA determines that an entity employee's continued eligibility is not in the interest of national security, the CSA implements procedures leading to suspension and ultimate revocation of the employee's eligible status, and notifies the entity.

(b) *Consultants.* A consultant is an individual under contract or agreement to provide professional or technical assistance to an entity in a capacity requiring access to classified information. A consultant is considered an entity employee for security purposes. The CSA makes eligibility determinations for entity consultants in the same way it does for entity employees.

(c) *Reciprocity.* The responsible CSA determines if an entity employee was previously investigated or determined eligible by another CSA. CSAs reciprocally accept existing employee eligibility determinations in accordance with applicable and current national level personnel security policy, and must not duplicate employee eligibility investigations conducted by another CSA.

(d) *Limited access authorization (LAA).* (1) CSAs may make LAA determinations for non-U.S. citizen entity employees in rare circumstances, when:

(i) A non-U.S. citizen employee possesses unique or unusual skill or expertise that the agency urgently needs to support a specific U.S. Government contract or agreement; and

(ii) A U.S. citizen with those skills is not available.

(2) A CSA may grant LAAs up to the secret classified level.

(3) CSAs may not use LAAs for access to:

(i) Top secret (TS) information;

(ii) RD or FRD information;

(iii) Information that a Government-designated disclosure authority has not determined releasable to the country of which the individual is a citizen;

(iv) COMSEC information;

(v) Intelligence information, to include SCI;

(vi) NATO information, except as follows: Foreign nationals of a NATO member nation may be authorized access to NATO information subject to the terms of the contract, if the responsible CSA obtains a NATO security clearance certificate from the individual's country of citizenship. NATO access is limited to performance on a specific NATO contract;

(vii) Information for which the U.S. Government has prohibited foreign disclosure in whole or in part; or

(viii) Information provided to the U.S. Government by another government that is classified or provided in confidence.

(4) The responsible CSA provides specific procedures to entities for requesting LAAs. The GCA must concur on an entity's LAA request before the CSA may grant it.

§ 2004.38 Safeguarding and marking.

(a) *Safeguarding approval.* (1) The CSA determines whether an entity's safeguarding capability meets requirements established in 32 CFR part 2001, and other applicable national level policy (*e.g.,* Atomic Energy Act for RD). If the CSA makes a favorable determination, the entity may store classified information at that level or below. If the determination is not favorable, the CSA must ensure that the entity does not possess classified information or does not possess information at the classification level denied or a higher level.

(2) The CSA maintains records of its safeguarding capability determinations and, upon request from GCAs or entities, and as appropriate and to the extent authorized by law, verifies that it has made a favorable safeguarding determination for a given entity and at what level.

(b) *Marking.* The GCA provides guidance to entities that meets requirements in 32 CFR 2001.22, 2001.23, 2001.24, and 2001.25, Derivative classification, Classification marking in the electronic environment, Additional requirements, and Declassification markings; ISOO's marking guide, *Marking Classified National Security Information;* and other applicable national level policy (*e.g.,* Atomic Energy Act for RD) for marking classified information and material.

§ 2004.40 Information system security.

(a) The responsible CSA must authorize an entity information system before the entity can use it to process classified information. The CSA must use the most complete, accurate, and trustworthy information to make a timely, credible, and risk-based decision whether to authorize an entity's system.

(b) The responsible CSA issues to entities guidance that establishes protection measures for entity information systems that process classified information. The responsible CSA must base the guidance on standards applicable to Federal systems, which must include the Federal Information Security Modernization Act of 2014 (FISMA), Public Law 113–283, and may include National Institute of Standards and Technology (NIST) publications, Committee on National Security Systems (CNSS) publications, and Federal information processing standards (FIPS).

§ 2004.42 [Reserved]

Appendix A to Part 2004—Acronym Table

For details on many of these terms, see the definitions at § 2004.4.

CCIPP—Classified Critical Infrastructure Protection Program
CCIPP POC—Entity point of contact under the CCIPP program
CIA—Central Intelligence Agency
CSA—Cognizant security agency
CNSS—Committee on National Security Systems
COMSEC—Communications security
CSO—Cognizant security office
DHS—Department of Homeland Security
DoD—Department of Defense
DOE—Department of Energy
EA—Executive agent (the NISP executive agent is DoD)
E.O.—Executive Order
FAR—Federal Aquisition Regulation
FOCI—Foreign ownership, control, or influence
GCA—Government contracting activity
Insider threat program SO—insider threat senior official (for an agency or for an entity)
ISOO—Information Security Oversight Office of the National Archives and Records Administration (NARA)
KMO—Key managers and officials (of an entity)
LAA—Limited access authorization
NID—National interest determination
NISPOM—National Industrial Security Program Operating Manual
NRC—Nuclear Regulatory Commission
NSA—National Security Agency
ODNI—Office of the Director of National Intelligence
PA—Proxy agreement
RD—Restricted data
SF—Standard Form
SAO—Senior agency official for NISP
SAP—Special access program
SCA—Security control agreement
SCI—Sensitive compartmented information
SSA—Special security agreement
TS—Top secret (classification level)

VT—Voting trust

David S. Ferriero,

Archivist of the United States.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0077]

RIN 1625–AA00

Safety Zone; Ohio River, Metropolis, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing an emergency temporary safety zone for all navigable waters of the Ohio River extending from mile marker (MM) 939.8 to MM 943.0 near Metropolis, IL. This emergency safety zone is needed to protect life, vessels, and the marine environment due to the sinking of one barge in the navigable channel of the Ohio River near MM 940.8 and one barge near the left descending bank at MM 942.5. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative.

DATES: This rule is effective without actual notice from 12:01 a.m. until 11:59 p.m. on May 7, 2018. For the purposes of enforcement, actual notice will be used from May 1, 2018 until May 7, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0077 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Joshua Herriott, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5343, email *SECOHV-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be impracticable and contrary to the public interest. On May 1, 2018, a towing vessel struck the I–24 Bridge near mile marker (MM) 940.8, causing 12 barges to break away. One barge sank near MM 940.8, and another sank near MM 942.5 on the left-descending bank. This safety zone must be established immediately to protect people and vessels associated with and resulting from the hazard to navigation created by the sunken barges and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. This safety zone includes closures and navigation restrictions and requirements that are vital to maintaining safe navigation on the Ohio River during the recovery of the sunken barges. Therefore, delaying the effective date for this emergency safety zone to complete the NPRM process would also be contrary to the public interest as it would delay the safety measures vital to safe navigation.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to protect personnel, vessels, and the marine environment from potential hazards created by the sunken barges.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the sunken barges will be a safety concern for anyone within MM 939.8 to MM 943.0 of the Ohio River, starting on May 1, 2018, and continuing 24 hours daily through 11:59 p.m. on May 7, 2018. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the sunken barges are being recovered.

IV. Discussion of the Rule

The Coast Guard is establishing a temporary emergency safety zone for all navigable waters of the Ohio River from MM 939.8 and MM 943.0, extending the entire width of the river. Entry is prohibited for all traffic beginning on May 1, 2018 and will continue to be prohibited through midnight on May 7, 2018 or until the hazard has been mitigated. The COTP will terminate the enforcement of this safety zone before May 7, 2018, if the sunken barges have been recovered. Entry into this safety zone is prohibited unless authorized by the COTP or his designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Ohio Valley.

Requests for entry will be considered and reviewed on a case-by-case basis. The COTP may be contacted by telephone at 502–779–5422 or can be reached by VHF–FM channel 16. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 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 rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule 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 determination is based on the limited size, location, and duration the safety zone, and the time of year. This safety zone will restrict vessel traffic from entering or transiting within a 3.2 mile area of navigable waterways on the Ohio River between MM 939.8 and MM 943.0. Moreover, the Coast Guard will issue 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 rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves an emergency safety zone lasting less than one week that will prohibit entry on a 3.2 mile stretch of the Ohio River during recovery of sunken barges. It is categorically excluded from further review under paragraph L60(c) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. Because this safety zone is established in response to an emergency situation and is less than one week in duration, a Record of Environmental Consideration (REC) is not required. Should this emergency situation require a safety zone lasting longer than one week, a REC will be made available as indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0077 to read as follows:

§ 165.T08–0077 Safety Zone; Ohio River, Metropolis, IL.

(a) *Location.* The following area is a safety zone: All navigable waters of the Ohio River from mile marker (MM) 939.8 to MM 943.0, extending the entire width of the river.

(b) *Enforcement period.* This section will be enforced from May 1, 2018, through May 7, 2018, or until the sunken barges are recovered, whichever occurs first.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or designated representative. A ''designated representative'' is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to

units under the operational control of USCG Sector Ohio Valley.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. To seek entry into the safety zone, contact the COTP or the COTP's representative by telephone at 502–779–5422 or on VHF–FM channel 16.

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

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and dates for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs), as appropriate.

Dated: May 2, 2018.

M.B. Zamperini,

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

[FR Doc. 2018–09662 Filed 5–4–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2018–0363]

Safety Zone; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone—Marinette Logging and Heritage Fest

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Marinette Logging and Heritage Festival Fireworks on the Menomonee River in Marinette, WI from 9 p.m. through 11 p.m. on July 14, 2018. This action is necessary and intended to ensure safety of life on navigable waters immediately prior to, during, and after the fireworks display. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated representative.

DATES: The regulations in 33 CFR 165.929 will be enforced for safety zone (e)(50), Table 165.929, from 9 p.m. through 11 p.m. on July 14, 2018.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email marine event coordinator, MSTC K. Carpino, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI; telephone (414) 747–7148, email *D09–SMB–SECLakeMichigan-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Marinette Logging and Heritage Festival Fireworks safety zone listed as item (e)(50) in Table 165.929 of 33 CFR 165.929 from 9 p.m. through 11 p.m. on July 14, 2018 on all waters of the Menominee River, in the vicinity of Stephenson Island, within the arc of a circle with a 900-foot radius from the fireworks launch site in position 45°06.232′ N, 087°37.757′ W (NAD 83). Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated on-scene representative.

This notice of enforcement is issued under authority of 33 CFR 165.929, Safety Zones; Annual events requiring safety zones in the Captain of the Port Lake Michigan zone, and 5 U.S.C. 552(a). In addition to this publication in the **Federal Register**, the Coast Guard plans to provide the maritime community with advance notification for the enforcement of this safety zone via Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port Lake Michigan or a designated representative will inform the public through a Broadcast Notice to Mariners of any changes in the planned schedule. The Captain of the Port Lake Michigan or a representative may be contacted via Channel 16, VHF–FM., or via telephone (414) 747–7182

Dated: April 19, 2018.

Thomas J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.

[FR Doc. 2018–09663 Filed 5–4–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0376]

RIN 1625–AA00

Safety Zone; Neches River, Beaumont, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone on navigable waters of the Neches River extending 500-feet on either side of the Kansas City Southern Railroad Bridge that crosses the Neches River in Beaumont, TX. The safety zone is necessary to protect the bridge as well as persons and property on or near the bridge from potential damage from passing vessels until missing and/or damaged fendering systems are repaired or replaced. Entry of certain vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Marine Safety Unit Port Arthur or a designated representative. We invite your comments on this rule.

DATES: This rule is effective without actual notice from May 7, 2018 through midnight on August 31, 2018. For the purposes of enforcement, actual notice will be used from May 1, 2018 through May 7, 2018. Comments and related material must be received before May 29, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0376 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comment'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0376 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Scott Whalen, Marine Safety Unit Port Arthur, U.S. Coast Guard; telephone 409–719–5086, email *Scott.K.Whalen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Marine Safety Unit Port Arthur
DHS Department of Homeland Security
FR Federal Register
KCS Kansas City Southern Railroad Company
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
VTS Vessel Traffic Service

II. Background Information and Regulatory History

On April 19, 2018, the Coast Guard was notified that the wood fendering systems designed to protect bridge support columns of the Kansas City Southern Railroad Company's bridge (KSC) from strikes by vessels transiting under the bridge had been damaged or destroyed by Hurricane Harvey. The south bank column protection fenders are missing and the north bank column protection fenders are severely damaged. KCS indicated that strikes to the support columns could compromise the bridge structure.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The fendering systems protecting the bridge from strikes by passing marine traffic are missing or severely damaged and we must establish this safety zone immediately to protect the bridge and those persons that use the bridge. The Coast Guard is providing an opportunity to comment while the rule is in effect and may amend the rule after it becomes effective, if necessary.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to respond to potential safety hazards posed by and to passing vessel traffic by and to the unprotected bridge columns supporting the KCS Bridge.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Marine Safety Unit Port Arthur (COTP) has determined that potential hazards posed by the unprotected bridge columns are a safety concern to the KCS Bridge and to persons and property on or near the bridge. The purpose of this rule is to provide for the safety of the KCS Bridge and persons and property on or near the bridge.

IV. Discussion of the Rule

This rule establishes a safety zone from 1 p.m. on May 1, 2018 through midnight on August 31, 2018 until missing and/or damaged fendering systems are repaired or replaced, whichever occurs first. The safety zone will extend 500-feet on either side of the KCS Bridge that crosses the Neches River in Beaumont, TX in approximate location 30° 04′54.8″ N 094°05′29.4″ W. The duration of the zone is intended to protect the bridge support columns as well as persons and property on or near the bridge until the bridge fendering is repaired or replaced. Only vessels less than 65 feet in length and not engaged in towing are authorized to enter the zone, unless otherwise permitted by the COTP or a designated representative are permitted to enter the safety zone.

Persons and vessels not permitted to enter the safety zone must request permission from the COTP or a designated representative. They may be contacted through Vessel Traffic Service (VTS) on channels 65A or 13 VHF–FM, or by telephone at (409) 719–5070.

Permission to transit through the bridge will be based on weather, tide and current conditions, vessel size, horsepower, and availability of assist vessels. All persons and vessels permitted to enter this temporary safety zone shall comply with the lawful orders or directions given to them by COTP or a designated representative.

Intentional or unintentional contact with any part of the bridge or associated structure, including fendering systems, support columns, spans or any other portion of the bridge, is strictly prohibited. Report any contact with the bridge or associated structures immediately to VTS Port Arthur on channels 65A, 13 or 16 VHF–FM or by telephone at (409) 719–5070.

The Coast Guard will inform the public through public of the effective period of this safety zone through VTS Advisories, Broadcast Notices to Mariners (BNMs), Local Notice to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 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 rule has not been designated as a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule 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 and duration of the safety zone. This rule will only affect certain vessels transiting the upper reaches of the Neches River in Beaumont, TX. The Coast Guard will issue a VTS Advisory concerning 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 rule will not have a significant economic impact on a substantial number of small entities.

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions

annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit entry within 500-feet of either side of the KCS Bridge that crosses the Neches River in Beaumont, TX. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

VI. 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. The Coast Guard may amend this temporary final rule if we receive comments from the public that indicate that a change is warranted. 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.

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** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this temporary final rule as being available in the docket, and all public comments, will be 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.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0376 to read as follows:

§ 165.T08–0376 Safety Zone; Neches River, Beaumont, TX.

(a) *Location.* The following area is a safety zone: all navigable waters extending 500-feet on either side of the Kansas City Southern Railroad Bridge that crosses the Neches River in Beaumont, TX in approximate location 30°04′54.8″ N 094°05′29.4″ W.

(b) *Effective period.* This section is effective from 1 p.m. on May 1, 2018 through midnight on August 31, 2018 or until missing and/or damaged fendering systems are repaired or replaced, whichever occurs first.

(c) *Regulations.* (1) No vessel may enter or remain in the safety zone except:

(i) A vessel less than 65 feet in length and not engaged in towing; or

(ii) A vessel authorized by the Captain of the Port Marine Safety Unit Port Arthur (COTP) or a designated representative

(2) Persons and vessels not permitted to enter the safety zone must request permission from the COTP or a designated representative. They may be contacted through Vessel Traffic Service (VTS) on channels 65A or 13 VHF–FM, or by telephone at (409) 719–5070.

(3) Permission to transit through the bridge will be based on weather, tide and current conditions, vessel size, horsepower, and availability of assist vessels. All persons and vessels permitted to enter this temporary safety zone shall comply with the lawful orders or directions given to them by COTP or a designated representative.

(4) Intentional or unintentional contact with any part of the bridge or associated structure, including

fendering systems, support columns, spans or any other portion of the bridge, is strictly prohibited. Report any contact with the bridge or associated structures immediately to VTS Port Arthur on channels 65A, 13 or 16 VHF–FM or by telephone at (409) 719–5070.

(d) *Informational broadcasts.* The Coast Guard will inform the public of the effective period of this safety zone through VTS Advisories, Broadcast Notices to Mariners (BNMs), Local Notice to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: May 1, 2018.

Jacqueline Twomey,

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

[FR Doc. 2018–09667 Filed 5–4–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0294; FRL–9977–31]

Duddingtonia flagrans strain IAH 1297; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities when used in accordance with label directions and good agricultural practices. International Animal Health Products Pty. Ltd. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Duddingtonia flagrans* strain IAH 1297 under FFDCA.

DATES: This regulation is effective May 7, 2018. Objections and requests for hearings must be received on or before July 6, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0294, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Director, 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).

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0294 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 6, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0294, by one of the following methods:

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

II. Background and Statutory Findings

In the **Federal Register** of October 23, 2017 (82 FR 49022) (FRL–9967–37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6F8531) by International Animal Health Products Pty. Ltd., 18 Healey Circuit, Huntingwood, New South Wales 2148, Australia (in care of SciReg. Inc., 12733 Director's Loop, Woodbridge, VA 22192). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all raw and processed agricultural commodities. That document referenced a summary of the petition prepared by the petitioner International Animal Health Products Pty. Ltd., which is available in the docket via *http://www.regulations.gov.*

There were no comments received in response to the notice of filing.

EPA changed the commodity to be reflected in the tolerance expression from ''in or on all raw and processed agricultural commodities'' to ''in or on all food commodities.'' The reason for this change is explained in Unit VII.B.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, for microbial pesticides, EPA determines the pathogenicity and toxicity of the pesticide. Second, EPA examines exposure to the pesticide through food, drinking water, and other exposures that occur as a result of pesticide use in residential settings, as well as other non-occupational exposure to the substance.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information on *Duddingtonia flagrans* strain IAH 1297 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of Duddingtonia flagrans Strain IAH 1297 (Refs. 1 and 2)

Duddingtonia flagrans is a fungus commonly found worldwide in soils, various plant materials, and animal feces that, in the presence of nematodes, forms looped adhesive network traps in animal feces in pasture when the diet of grazing animals is supplemented with the fungus' chlamydospores or the chlamydospores are acquired naturally from soil or plant material while the animals graze. *Duddingtonia flagrans* strain IAH 1297 chlamydospores can survive passage through the rumen and gastrointestinal tract after ingestion by grazing animals and then germinate on pasture (*i.e.,* the chlamydospores do not germinate in animals and cannot grow at normal body temperature or under anaerobic conditions). Nematode eggs excreted by pastured or wild animals hatch in the presence of *Duddingtonia flagrans* strain IAH 1297. Thereafter, *Duddingtonia flagrans* strain IAH 1297 passively traps nematodes, penetrates the nematode cuticle and kills them within 4–8 hours, occupies the nematode body with hyphae within 20–36 hours, and consumes nematodes within 48 hours, thus breaking the infection excretion and reinfection cycle of nematodes. *Duddingtonia flagrans* strain IAH 1297's use as a feed-through nematicide comes as growing anthelmintic (antiparasitic drug) resistance and general lack of new drug options to treat affected animals is becoming a concern.

B. Microbial Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities have been fulfilled with data submitted by the petitioner or data waiver requests that have been granted by EPA. The toxicity tests (acute oral and dermal) and the primary dermal irritation test that address potential routes of exposure to the active ingredient are all classified in Toxicity Category IV (see section II of Ref. 3) and reveal no toxicity or irritation attributed to *Duddingtonia flagrans* strain IAH 1297. Moreover, during typical toxicity/pathogenicity testing done with microbial pesticides, *Duddingtonia flagrans* strain IAH 1297 showed no toxicity, pathogenicity, or infectivity via the pulmonary route of exposure. The conclusions and classifications from all toxicological information associated with the active ingredient and submitted by the petitioner are briefly described below.

1. *Acute oral toxicity—rat (Harmonized Guideline 870.1100; Master Record Identification Number (MRID) No. 503887–01).* An acceptable acute oral toxicity study demonstrated that *Duddingtonia flagrans* strain IAH 1297 is not toxic to female rats when dosed via the oral route at 5,000 milligrams per kilogram (mg/kg) of bodyweight. The oral median lethal dose (LD_{50}), which is a statistically derived single dose that can be expected to cause death in 50% of test animals, was greater than 5,000 mg/kg of bodyweight for female rats (Toxicity Category IV). (Refs. 1 and 2).

2. *Acute oral toxicity/pathogenicity (Harmonized Guideline 885.3050; MRID Nos. 501117–14 and 501117–27).* An acceptable scientific rationale was submitted by the petitioner; therefore, EPA waived acute oral toxicity/pathogenicity testing for *Duddingtonia flagrans* strain IAH 1297. An acute oral toxicity study conducted on female rats (MRID No. 503887–01) demonstrated that *Duddingtonia flagrans* strain IAH 1297 was not toxic (LD_{50} greater than 5,000 mg/kg; Toxicity Category IV). Further, field studies were conducted on animal groups in Australia under direction of veterinarians. A 56-day study using young cattle demonstrated that a test substance containing *Duddingtonia flagrans* strain IAH 1297 had no discernible health effects when given with feed at 125 grams per 100 kilograms of bodyweight per day (representing 10X the label use rate). A 42-day study using Merino ewes had no findings attributable to treatment with a test substance containing *Duddingtonia flagrans* strain IAH 1297, and both groups had statistically similar weight gains throughout at 1 kilogram per group per day (representing 5X the label use rate). A 56-day study using horses demonstrated that a test substance containing *Duddingtonia flagrans* strain IAH 1297 had no discernible health effects when given with feed at 1 gram per kilogram bodyweight per day (representing 10X the label use rate). No signs of any infection were observed during these lengthy studies. EPA believes these data, when taken together, indicate that this fungus would not be toxic, infective, and/or pathogenic through the oral route of exposure and that further testing is not necessary. (Refs. 1 and 2).

3. *Acute pulmonary toxicity/pathogenicity—rat (Harmonized Guideline 885.3150; MRID Nos. 501117–*

15, 501117–16, 505317–00, and 505318–00). An acceptable acute pulmonary toxicity/pathogenicity study performed with *Duddingtonia flagrans* strain IAH 1297 did not induce signs of toxicity, infectivity, or pathogenicity when administered to rats as a single, intratracheal dose of 5.8×10^4 spores per animal. Additionally, clearance was established by day 42 of the test. (Refs. 1, 2, and 4).

4. *Acute injection toxicity/pathogenicity (Harmonized Guideline 885.3200; MRID No. 501117–17).* An acceptable scientific rationale was submitted by the petitioner; therefore, EPA waived acute injection toxicity/pathogenicity testing for *Duddingtonia flagrans* strain IAH 1297. Intratracheal pulmonary administration of the highest possible dose of *Duddingtonia flagrans* strain IAH 1297 did not show any sign of infection or pathogenicity (MRID No. 501117–16). Lengthy oral dosing of cattle, sheep, and horses demonstrated no effects at doses of 5–10X the label use rates (MRID No. 501117–27), and an oral dose of 5,000 mg/kg of bodyweight to female rats also demonstrated no effects (MRID No. 503887–01). Further, injection is expected to result in minimal breakdown of spores, and the relatively large size of the spores makes injection testing impractical. The lack of growth when *Duddingtonia flagrans* strain IAH 1297 was tested at 37°C (oral dosing) also allays the need to test infectivity and pathogenicity by the injection route. *Duddingtonia flagrans* strain IAH 1297 has not shown any ability to germinate or grow when mammals were exposed by various other routes, and injection of these large spores is not expected to result in infection even if possible to perform the test. Thus, EPA believes these data and information, when taken together, indicate that this fungus would not be toxic, infective, and/or pathogenic through the injection route of exposure and that further testing is not necessary. (Refs. 1 and 2).

5. *Acute dermal toxicity—rat (Harmonized Guideline 870.1200; MRID No. 501113–05).* An acceptable acute dermal toxicity study conducted using a test substance containing *Duddingtonia flagrans* strain IAH 1297 demonstrated that the fungus was not toxic to rats when dosed at 5,000 mg/kg of bodyweight for 24 hours to a body surface area of approximately 10 percent. Following exposure, animals were observed for 14 days. All animals survived, gained weight, appeared active and healthy, and had no signs of dermal irritation throughout the study. No observable abnormalities were found in any animal at necropsy. The dermal LD_{50} for male and female rats combined was greater than 5,000 mg/kg of bodyweight (Toxicity Category IV). (Refs. 1 and 2).

6. *Primary dermal irritation—rabbit (Harmonized Guideline 870.2500; MRID No. 501113–07*). An acceptable primary dermal irritation study conducted using a test substance containing *Duddingtonia flagrans* strain IAH 1297 demonstrated that the fungus was non-irritating to the skin of rabbits. No dermal erythema, edema, or irritation was noted on any animal during the study. The primary irritation index was 0.0, and all animals gained weight normally during the study (Toxicity Category IV). (Refs. 1 and 2).

IV. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure (Refs. 1 and 2)

1. *Food exposure.* The proposed use of *Duddingtonia flagrans* strain IAH 1297 is as a feed-through product for grazing animals such as sheep, goats, cattle, horses, deer, alpacas and zoo animals. As *Duddingtonia flagrans* is naturally present in soils and commonly found in various plant materials, it is likely that grazing animals have natural background exposure to the fungus. No adverse effects have been reported as a result of these types of exposures. Studies performed with *Duddingtonia flagrans* strain IAH 1297 have not shown that this strain has the ability to germinate or grow when mammals are exposed by various routes, including the oral route. Further, no foodborne disease outbreaks or cases of mammalian toxin production from *Duddingtonia flagrans* have been reported. As a result, dietary exposure to *Duddingtonia flagrans* strain IAH 1297 through agricultural commodities is not anticipated from use of the pesticide products as the spores and/or components of the spores are unlikely to remain in the treated animals. Should *Duddingtonia flagrans* strain IAH 1297 be present in food, however, supporting toxicological data and information indicate that no toxicity, pathogenicity, or infectivity is likely to occur with this type of exposure resulting from the use of this microbial pesticide when applied in accordance with label directions and good agricultural practices.

2. *Drinking water exposure.* Since *Duddingtonia flagrans* is naturally present in the environment and *Duddingtonia flagrans* strain IAH 1297 will be present in the feces of treated animals, exposure to surface and possibly groundwater can be expected. Water treatment processes should remove any *Duddingtonia flagrans* or *Duddingtonia flagrans* strain IAH 1297 present in these water sources, and no adverse effects have been reported from exposure to *Duddingtonia flagrans* through drinking water. As a result, dietary exposure to *Duddingtonia flagrans* strain IAH 1297 through drinking water is not anticipated from use of the pesticide products as the spores and/or components of the spores are unlikely to survive the water treatment process. Should *Duddingtonia flagrans* strain IAH 1297 be present in water, however, supporting toxicological data and information indicate that no toxicity, pathogenicity, or infectivity is likely to occur with this type of exposure resulting from the use of this microbial pesticide when applied in accordance with label directions and good agricultural practices.

B. Other Non-Occupational Exposure

The pesticide products containing *Duddingtonia flagrans* strain IAH 1297 are proposed for agricultural use sites and zoos. As a result, residential exposures resulting from use of these products are not anticipated. Nevertheless, *Duddingtonia flagrans* strain IAH 1297 was not toxic or irritating by dermal exposure and was not toxic, infective, or pathogenic by pulmonary exposure. Further, the products are mixed into feed ingredients at 2–34.6% so it is not in pure form, and the spore size is at the upper end of the respirable range so human exposures to *Duddingtonia flagrans* strain IAH 1297 by inhalation from contact with animal feed supplements is unlikely.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

Duddingtonia flagrans strain IAH 1297 is not toxic and does not have a common mechanism of toxicity with other substances. Consequently, FFDCA section 408(b)(2)(D)(v) does not apply.

VI. Determination of Safety for U.S. Population, Infants and Children

A. U.S. Population

For all of the reasons discussed previously, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Duddingtonia flagrans* strain IAH 1297. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

B. Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. As discussed above, EPA has concluded that *Duddingtonia flagrans* strain IAH 1297 is not toxic, pathogenic, or infective to mammals, including infants and children. Because there are no threshold levels of concern to infants, children, and adults when *Duddingtonia flagrans* strain IAH 1297 is used in accordance with label directions and good agricultural practices, EPA concludes that no additional margin of safety is necessary to protect infants and children.

VII. Other Considerations

A. Analytical Enforcement Methodology

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

B. Revisions to Requested Tolerance Exemption

One modification has been made to the requested tolerance exemption. EPA is changing ''in or on all raw and processed agricultural commodities'' to ''in or on all food commodities'' to align with the terminology the Agency currently uses when establishing tolerance exemptions for residues of other like active ingredients.

VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Duddingtonia flagrans* strain IAH 1297. Therefore, an exemption from the requirement of a tolerance is established for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities when used in accordance with label directions and good agricultural practices.

IX. References

1. U.S. EPA. 2017. *Duddingtonia flagrans* strain IAH 1297. Memorandum from J.V. Gagliardi, Ph.D. through M.J. Perry to M. Glikes, dated October 17, 2017 (available as a ''Supporting Document'' within Docket ID Number EPA–HQ–OPP–2017–0296 at *http://www.regulations.gov*).
2. U.S. EPA. 2018. *Duddingtonia flagrans* strain IAH–1297 (PC Code 033000)—Human Health Risk Assessment Summary. Memorandum from M. Perry through J. Kough, Ph.D. to C. Kendrick, dated March 26, 2018 (available as a ''Supporting Document'' within Docket ID Number EPA–HQ–OPP–2017–0296 at *http://www.regulations.gov*).
3. U.S. EPA. 2014. Chapter 7 of the Label Review Manual (Precautionary Statements) (Revised July 2014). Available from *https://www.epa.gov/sites/production/files/2015-03/documents/chap-07-jul-2014.pdf.*
4. U.S. EPA. 2018. *Duddingtonia flagrans* strain IAH–1297. Memorandum from J.V. Gagliardi, Ph.D. through J.L. Kough, Ph.D. to C. Kendrick, dated March 27, 2018 (available as a ''Supporting Document'' within Docket ID Number EPA–HQ–OPP–2017–0296 at *http://www.regulations.gov*).

X. Statutory and Executive Order Reviews

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

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

XI. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,

Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 26, 2018.

Wynne Miller,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Add § 180.1355 to subpart D to read as follows:

§ 180.1355 Duddingtonia flagrans strain IAH 1297; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Duddingtonia flagrans* strain IAH 1297 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2018–09647 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0249; FRL–9976–60]

Konjac Glucomannan; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of konjac glucomannan (CAS Reg. No. 37220–17–0) when used as an inert ingredient on growing crops only at a concentration not to exceed 1% by weight in a pesticide formulation. Technology Services Group, on behalf of, Attune Agriculture, LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of konjac glucomannan resulting from use in accordance with the terms of this exemption.

DATES: This regulation is effective May 7, 2018. Objections and requests for hearings must be received on or before July 6, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0249, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0249 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 6, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0249, by one of the following methods:

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

II. Petition for Exemption

In the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL–9965–43), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11048) by Technology Services Group, on behalf of, Attune Agriculture, LLC, 10552 Philadelphia Road, White Marsh, MD 21162. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of konjac glucomannan (also referred to as konjac mannan) (CAS Reg. No. 37220–17–0)

when used as an inert ingredient (thickener) in pesticide formulations applied to growing crops only at a maximum use level of 1.0%. That document referenced a summary of the petition prepared by Technology Services Group, on behalf of, Attune Agriculture, LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response is discussed in Unit V.C.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by konjac glucomannan as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Konjac glucomannan is a non-digestible polysaccharide with a large molecular weight (*i.e.,* 200,000–2,000,000 daltons). A substance of this size would be unlikely to penetrate intact human skin or gastrointestinal tract. Because of its large molecular weight and the body's inability to digest it, it is unlikely that the body will absorb konjac glucomannan. This is supported by the studies below.

Often in the literature, konjac flour and konjac glucomannan are used interchangeably. The European Commission defines konjac flour as the unpurified raw product from the root of the perennial plant *Amorphophallus konjac,* and konjac glucomannan refers to the product that has been washed and extracted using water-containing ethanol. The majority of the studies refer to the use of konjac flour as the test substance. EPA has concluded that it is appropriate to rely on those studies since the two substances are essentially the same in molecular weight and origin thus expected to present the same toxicological profile.

Konjac glucomannan exhibits low levels of acute toxicity. Acute studies in rats and mice show oral LD_{50s} of >2,800 mg/kg to >5,000 mg/kg. The dermal LD_{50} in rabbits is >2,000 mg/kg. Konjac glucomannan was not shown to be a skin irritant or dermal sensitizer and shows minimal eye irritation.

Asthmatic responses in humans (*e.g.,* Konjac asthma or *konnyaku* asthma) exposed to airborne powders produced during commercial manufacture of konjac flour from konjac tubers has been reported. It has been associated with the inhalation of dust produced during the production of konjac flour to make konnyaku, a traditional jelly-like Asian food prepared from glucomannan. An inhalation exposure study with guinea pigs demonstrated that respiratory hypersensitivity to food grade konjac flour can be induced following repeated inhalation exposures. According to a more recent study, however, the antigen in konjac flour responsible for respiratory sensitization is actually a protein and not glucomannan.

Several repeat-dose toxicity studies conducted on Sprague-Dawley rats are available for konjac flour: A four-week dietary study, a twelve-week feeding study, an 18-month dietary study, and an 8-week oral study with pregnant cats. Two carcinogenicity studies are also available.

A four-week dietary exposure study was conducted with Sprague-Dawley rats. Groups of four male rats were fed either 5% cellulose (control), 10% cellulose, 10% pectin or 10% konjac (~5,000 mg/kg/day) for 28 days. Compared to the control group, consumption of 10% konjac in the diet decreased the digestion and absorption of protein in the large intestine which resulted in a decrease in body weight gain. Because of the high dosing it is not certain if the effect seen is the result of excessive dosing or from the toxicity of chemical.

In a twelve-week feeding study, groups of 12/sex, five week old Sprague-Dawley rats received the basal diet (a 1% cholesterol) or konjac meal

supplementation at 2.5, 5.0 or 10% of the diet (~1,250, 2,500, or 5,000 mg/kg/day). Changes were seen on gross examination of the liver. The full study report was not available but according to the Food and Agriculture Organization/World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives (JECFA) report, the author suggests the reason for this is that konjac flour binds with bile acids and depresses reabsorption in the intestines which consequently reduces the accumulation of lipids in the liver. All treated groups had reduced total cholesterol in comparison with the high-cholesterol control group. Body-weight gain was slightly but statistically significantly lower in males fed 10% refined konjac meal than in the other groups during the first eight weeks. Food intake was also reduced in this group. Therefore, the NOAEL is 5% of the diet (~2,500 mg/kg/day) with a LOAEL of 10% (~5,000 mg/kg/day) based on decreased body weight gain in males.

An 18-month dietary study assessed groups of 15 Sprague-Dawley rats fed a basal diet or a diet with 1.0% konjac flour (~500 mg/kg/day). There was no difference in body weight gain, absolute or relative organ weights or femur weights and no evidence of treatment-related pathological changes or effects on calcium and phosphorus metabolism. Treated male rats had significantly lower serum cholesterol levels at 9 and 18 months and lower triglycerides at 3 and 9 weeks but not 12 months. In female rats, the only difference from the control was a lower triglyceride level at 18 months. The liver of treated rats had smaller more lightly stained nuclei and reduced bile duct proliferation in the portal area. Certain cells (not specified) of treated rats displayed fewer signs of senescence compared to controls. There was no evidence that 1% konjac flour in the diet (~500 mg/kg/day) was toxic to rats.

Two groups of 15 adult pregnant British short-hair cats were fed diets containing either 2% carob gum or 2% konjac flour (0.98 to 3.08 mg/kg/day prior to parturition) for eight weeks. There were no significant changes in body weight between controls and treated animals. Biochemical and hematological parameters were reported to be within normal ranges throughout the study. Mean birth weight of kittens born to control cats was statistically significantly lower ($p \leq 0.01$) than kittens born to konjac fed cats; however, the standard deviation was within the range of controls and therefore, these effects are not considered adverse. All cats in the study completed lactation and reared successfully.

There is no evidence that konjac glucomannan suppresses or otherwise harms immune function in mammalian systems. No signs of neurotoxicity were reported in the studies of acute or repeat-dose oral exposure to konjac glucomannan.

Genotoxicity tests of konjac flour include an Ames test, a mouse lymphoma assay, and an *in vivo* mouse micronucleus test. All genotoxicity assays were negative. Konjac was not mutagenic in the Ames test and did not induce mutations in cultured mouse lymphoma cells or cause clastogenicity in the *in vivo* micronucleus study in the presence or absence of S–9 activation.

Konjac glucomannan is not expected to be carcinogenic. In addition to showing negative results in genotoxicity and mutagenicity tests, a 20-week and a 1-year feeding study were conducted and no evidenced of carcinogenicity was observed. In fact, the incidence of colon tumors in 1,2-dimethylhydrazine DMH treated animals was significantly reduced with konjac glocomannan consumption. Similarly, spontaneous liver tumors in C3H/He mice were inhibited by maintaining the mice on a diet containing 10% glucomannan.

B. Toxicological Points of Departure/Levels of Concern

No toxicological endpoint of concern has been identified for konjac glucomannan. Based on the available information as discussed in Unit IV.A., it is concluded that there is no end point of concern identified and therefore, quantitative risk assessment is not warranted.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to konjac glucomannan, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from konjac glucomannan in food as follows:

Dietary exposure (food and drinking water) to konjac glucomannan may occur following ingestion of foods with residues from treated crops. Additional dietary exposure may result from the use of konjac glucomannan as a food additive; it has been used as a thickener, texture stabilizer, emulsifier, and gelling agent in foods and beverages, as well as agriculture and animal feed. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use on food crops.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Although currently, there are no uses for konjac glucomannan in products that might result in residential exposure, it is possible that some may be requested in the future. Additional non-dietary exposure may occur from use of konjac glucomannan in pharmaceutical products and cosmetics. Based on the discussion above, a quantitative residential exposure assessment for konjac glucomannan was not conducted.

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

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

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) requires EPA to retain an additional tenfold margin of safety in the case of threshold effects to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. As noted in Unit IV.B., there is no indication of threshold effects being caused by konjac glucomannan. Therefore, this requirement does not

apply to the present analysis. Moreover, due to the lack of any toxicological endpoints of concern, EPA is conducting a qualitative assessment of konjac glucomannan, which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on konjac glucomannan, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to konjac glucomannan. Therefore, EPA concludes that the exemption from the requirement of a tolerance as requested by the petitioner—for residues of konjac glucomannan on growing crops when used as an inert ingredient (thickener), in pesticide formulations at a concentration not to exceed 1.0% by weight of the pesticide formulation is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of konjac glucomannan in or on any food commodities. EPA is establishing limitations on the amount of konjac glucomannan that may be used in pesticide formulations applied to growing crops. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops for sale or distribution that exceeds 1% by weight of konjac glucomannan.

B. Response to Comments

One comment was received in response to the Notice of Filing. The comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute. EPA has evaluated all the available data and concluded that there is a reasonable certainty of no harm from the limited use of konjac glucomannan as inert ingredients in pesticide formulations. The commenter has not provided any information supporting a conclusion that this exemption would not be safe.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for konjac glucomannan (CAS Reg. No. 37220–17–0) when used as an inert ingredient (thickener) in pesticide formulations applied to growing crops only at a concentration not to exceed 1.0% by weight of the pesticide formulation.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 12, 2018.

Donna Davis,

Acting Division Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, add alphabetically the inert ingredient ''Konjac glucomannan (CAS Reg. No. 37220–17–0)'' to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * *	* *	*
Konjac glucomannan (CAS Reg. No. 37220–17–0)	Not to exceed 1.0% by weight in pesticide formulation.	Thickener.
* * * *	* *	*

[FR Doc. 2018–09649 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 90

[DA 18–282]

Modification of Rules To Codify New Procedure for Non-Federal Public Safety Entities To License Federal Interoperability Channels

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document adopts changes to the Commission's rules to conform them to a streamlining modification recently made by the National Telecommunications and Information Administration (NTIA). NTIA streamlined the coordination process which enables the Commission to grant licenses to non-federal public safety entities who seek to operate on forty federal government interoperability channels over which NTIA has jurisdiction.

DATES: Effective June 6, 2018, except for the addition of § 90.25, which contains a new information collection that requires review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The FCC will publish a document in the **Federal Register** announcing the effective date of that rule section.

FOR FURTHER INFORMATION CONTACT: Brian Marenco, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–0838.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, DA 18–282, released on March 22, 2018. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). The complete text of this document is also available on the Commission's website at *http://www.fcc.gov.*

1. NTIA designated forty channels for interoperability communications among federal agencies and between federal agencies and non-federal entities with which federal agencies have a requirement to interoperate. A non-federal public safety entity may communicate on the federal interoperability channels for joint federal/non-federal operations, provided it first obtains a license from the Commission authorizing use of the channels.

2. In September 2015, NTIA streamlined the process which enables non-federal agencies to obtain an FCC license to use the federal interoperability channels. Under the new process, the Statewide Interoperability Coordinator (SWIC) or state appointed official in each state is responsible for coordinating access to the federal interoperability channels by non-federal public safety entities. Each SWIC/official will sign an agreement with a federal user with a valid assignment. The agreement may specify which federal interoperability channels are available for use in a particular state or territory and establish the conditions for their use by non-federal public safety entities.

3. Once the federal-state agreement for a given state is signed, non-federal public safety entities in that state may file an application with the Commission to license the designated federal interoperability channels under the new streamlined process. Before filing with the Commission, a non-federal public safety entity seeking to license mobile and portable units on the federal government interoperability channels must first obtain written concurrence from its SWIC/official. The non-federal agency must then include a copy of the written concurrence with its license application to the Commission.

4. NTIA's streamlined process eliminates the need for non-federal public safety entities to obtain written certification from a federal government agency and for the Commission to refer applications for the federal interoperability channels to the Interdepartment Radio Advisory Committee's (IRAC) Frequency Assignment Subcommittee for approval.

5. On March 22, 2018, the Public Safety and Homeland Security Bureau and the Office of Engineering and Technology, on delegated authority, jointly released an Order amending §§ 2.102(c)(4) and 90.173(c) and adopting new § 90.25 in order to conform the Commission's rules to the new streamlined process established by NTIA.

Procedural Matters

A. Paperwork Reduction Act of 1995 Analysis

6. The requirement in new § 90.25 that non-federal public safety agencies obtain written concurrence from the SWIC/official constitutes a new information collection subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review and public comment under section 3507(d) of the PRA.

7. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198 (see 44 U.S.C. 3506(c)(4)), the Commission's Public Safety and Homeland Security Bureau will seek specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

B. Congressional Review Act

8. The Commission will not send a copy of this Order pursuant to the Congressional Review Act, see 5 U.S.C.

801(a)(1)(A), because the adopted rules are rules of agency organization, procedure, or practice that do not ''substantially affect the rights or obligations of non-agency parties.

Ordering Clauses

9. Accordingly, *it is ordered*, pursuant to sections 4(i), 303(c) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(c), and 332, this *order is hereby adopted.*

10. *It is further ordered* that the rules and requirements adopted herein *will become* effective June 6, 2018, except for new § 90.25 that contains a new or modified information collection requirement that requires review by the OMB under the PRA. Section 90.25 *will become effective* after OMB review and approval, on the effective date specified in a notice that the Commission will publish in the **Federal Register** announcing such approval and effective date.

11. This action is taken under delegated authority pursuant to section 155(c) of the Communications Act of 1934, as amended, 47 U.S.C. 155(c) and §§ 0.31, 0.191, 0.241, and 0.392 of the Commission's rules, 47 CFR 0.31, 0.191, 0.241, and 0.392.

List of Subjects

47 CFR Part 2

Radio, Telecommunications.

47 CFR Part 90

Administrative practice and procedure, Radio.

Federal Communications Commission.

Lisa Fowlkes,

Chief, Public Safety and Homeland Security Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 2 and 90 as follows.

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 2. Amend § 2.102 by revising paragraph (c) to read as follows:

§ 2.102 Assignment of frequencies.

* * * * *

(c) Non-Federal stations may be authorized to use Federal frequencies in the bands above 25 MHz:

(1) If the Commission finds, after consultations with the appropriate Federal agency or agencies, that such use is necessary for coordination of Federal and non-Federal activities. Such operations must meet the following requirements:

(i) Non-Federal operation on Federal frequencies shall conform with the conditions agreed upon by the Commission and NTIA;

(ii) Such operations shall be in accordance with NTIA rules governing the service to which the frequencies involved are allocated;

(iii) Such operations shall not cause harmful interference to Federal stations and, should harmful interference result, that the interfering non-Federal operation shall immediately terminate; and

(iv) Non-Federal operation has been certified as necessary by the Federal agency involved and this certification has been furnished, in writing, to the non-Federal licensee with which communication is required; or

(2) Pursuant to the provisions of § 90.25 of this chapter, provided that such operations shall not cause harmful interference to Federal stations and, should harmful interference result, that the interfering non-Federal operation shall immediately terminate.

* * * * *

■ 3. Amend § 2.106 by revising pages 24 and 27 of the Table of Frequency Allocations, and by adding footnote US55 to the list of United States (US) Footnotes to read as follows:

§ 2.106 Table of Frequency Allocations.

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			157.1875-161.575	157.1875-157.45 MOBILE except aeronautical mobile US266 5.226 NG111	Maritime (80) Aviation (87) Private Land Mobile (90)
				157.45-161.575 FIXED LAND MOBILE NG28 NG111 NG112 5.226 NG6 NG70 NG124 NG148 NG155	Public Mobile (22) Remote Pickup (74D) Maritime (80) Private Land Mobile (90)
			161.575-161.625 5.226 US52	161.575-161.625 MARITIME MOBILE 5.226 US52 NG6 NG17	Public Mobile (22) Maritime (80)
			161.625-161.9625	161.625-161.775 LAND MOBILE NG6 5.226	Public Mobile (22) Remote Pickup (74D) Low Power Auxiliary (74H)
				161.775-161.9625 MOBILE except aeronautical mobile US266 NG6	Maritime (80) Private Land Mobile (90)
5.226	5.226		US266	5.226	
161.9625-161.9875 FIXED MOBILE except aeronautical mobile Mobile-satellite (Earth-to-space) 5.228F 5.226 5.228A 5.228B	161.9625-161.9875 AERONAUTICAL MOBILE (OR) MARITIME MOBILE MOBILE-SATELLITE (Earth-to-space) 5.228C 5.228D	161.9625-161.9875 MARITIME MOBILE Aeronautical mobile (OR) 5.228E Mobile-satellite (Earth-to-space) 5.228F 5.226	161.9625-161.9875 AERONAUTICAL MOBILE (OR) (AIS 1) MARITIME MOBILE (AIS 1) MOBILE-SATELLITE (Earth-to-space) (AIS 1) 5.228C US52		Satellite Communications (25) Maritime (80)
161.9875-162.0125 FIXED MOBILE except aeronautical mobile 5.226 5.229	161.9875-162.0125 FIXED MOBILE 5.226		161.9875-162.0125	161.9875-162.0125 MOBILE except aeronautical mobile 5.226	Maritime (80)
162.0125-162.0375 FIXED MOBILE except aeronautical mobile Mobile-satellite (Earth-to-space) 5.228F 5.226 5.228A 5.228B 5.229	162.0125-162.0375 AERONAUTICAL MOBILE (OR) MARITIME MOBILE MOBILE-SATELLITE (Earth-to-space) 5.228C 5.228D	162.0125-162.0375 MARITIME MOBILE Aeronautical mobile (OR) 5.228E Mobile-satellite (Earth-to-space) 5.228F 5.226	162.0125-162.0375 AERONAUTICAL MOBILE (OR) (AIS 2) MARITIME MOBILE (AIS 2) MOBILE-SATELLITE (Earth-to-space) (AIS 2) 5.228C US52		Satellite Communications (25) Maritime (80)
162.0375-174 FIXED MOBILE except aeronautical mobile	162.0375-174 FIXED MOBILE		162.0375-173.2 FIXED MOBILE US8 US11 US13 US55 US73 US300 US312 G5	162.0375-173.2 US8 US11 US13 US55 US73 US300 US312	Remote Pickup (74D) Private Land Mobile (90)
			173.2-173.4	173.2-173.4 FIXED Land mobile	Private Land Mobile (90)
			173.4-174 FIXED MOBILE	173.4-174	
5.226 5.229	5.226 5.230 5.231 5.232		G5		Page 24

Table of Frequency Allocations			400.15-456 MHz (UHF)		Page 27
International Table			United States Table		FCC Rule Part(s)
Region 1 Table	Region 2 Table	Region 3 Table	Federal Table	Non-Federal Table	
400.15-401 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) 5.208A 5.208B 5.209 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.262 5.264			400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	Satellite Communications (25)
401-402 METEOROLOGICAL AIDS SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile			401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US64 US384	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US64 US384	MedRadio (95I)
402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile			402-403 METEOROLOGICAL AIDS (radiosonde) US70 EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US64 US384	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US64 US384	
403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile			403-406 METEOROLOGICAL AIDS (radiosonde) US70 US64 G6	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US64	
406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267			406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267		Maritime (EPIRBs) (80V) Aviation (ELTs) (87F) Personal Radio (95)
406.1-410 FIXED MOBILE except aeronautical mobile RADIO ASTRONOMY 5.149			406.1-410 FIXED MOBILE RADIO ASTRONOMY US74 US13 US55 US117 G5 G6	406.1-410 RADIO ASTRONOMY US74 US13 US55 US117	Private Land Mobile (90)
410-420 FIXED MOBILE except aeronautical mobile SPACE RESEARCH (space-to-space) 5.268			410-420 FIXED MOBILE SPACE RESEARCH (space-to-space) 5.268 US13 US55 US64 G5	410-420 US13 US55 US64	Private Land Mobile (90) MedRadio (95I)

* * * * *

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United States (US) Footnotes

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US55 In the bands 162.0375–173.2 MHz and 406.1–420 MHz, the FCC may

authorize public safety applicants to use the 40 Federal Interoperability Channels that are designated for joint federal/non-federal operations for law enforcement, public safety, emergency response and disaster response in section 4.3.16 of the NTIA Manual, subject to the condition that that these non-Federal mobile (including portable) interoperability communications shall conform to the national plans specified therein, and in particular, shall not cause harmful interference to Federal stations. The procedure for authorizing such use is set forth in 47 CFR 90.25.

* * * * *

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 4. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), and 332(c)(7), and Title VI of the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, 126 Stat. 156.

■ 5. Add § 90.25 to subpart B to read as follows.

§ 90.25 Non-Federal Use of the Federal Interoperability Channels.

The Commission may authorize non-Federal licensees to operate mobile and portable radio units on the frequencies listed below in Tables 1 and 2, provided the applicant includes with its application to the Commission, written concurrence from the Statewide Interoperability Coordinator (SWIC) or state appointed official stating that the application conforms to the agreement with a federal agency with a valid assignment from the National Telecommunications and Information Administration.

TABLE 1—LAW ENFORCEMENT PLANS (MHZ)

LE VHF plan			LE UHF plan		
Identifier	Mobile transmit	Mobile receive	Identifier	Mobile transmit	Mobile receive
LEA	167.0875 (S)	167.0875	LEB	414.0375 (S)	414.0375
LE1	162.0875	167.0875	LE10	418.9875	409.9875
LE2	162.2625	167.2500	LE11	419.1875	410.1875
LE3	162.8375	167.7500	LE12	419.6125	410.6125
LE4	163.2875	168.1125	LE13	414.0625 (S)	414.0625
LE5	163.4250	168.4625	LE14	414.3125 (S)	414.3125
LE6	167.2500 (S)	167.2500	LE15	414.3375 (S)	414.3375
LE7	167.7500 (S)	167.7500	LE16	409.9875 (S)	409.9875
LE8	168.1125 (S)	168.1125	LE17	410.1875 (S)	410.1875
LE9	168.4625 (S)	168.4625	LE18	410.6125 (S)	410.6125

(S)—Simplex.

TABLE 2—INCIDENT RESPONSE PLANS (MHZ)

LE VHF Plan			LE UHF Plan		
Identifier	Mobile transmit	Mobile receive	Identifier	Mobile transmit	Mobile receive
NC1 Calling	164.7125	169.5375	NC2 Calling	419.2375	410.2375
IR1	165.2500	170.0125	IR10	419.4375	410.4375
IR2	165.9625	170.4125	IR11	419.6375	410.6375
IR3	166.5750	170.6875	IR12	419.8375	410.8375
IR4	167.3250	173.0375	IR13	413.1875 (S)	413.1875
IR5	169.5375 (S)	169.5375	IR14	413.2125 (S)	413.2125
IR6	170.0125 (S)	170.0125	IR15	410.2375 (S)	410.2375
IR7	170.4125 (S)	170.4125	IR16	410.4375 (S)	410.4375
IR8	170.6875 (S)	170.6875	IR17	410.6375 (S)	410.6375
IR9	173.0375 (S)	173.0375	IR18	410.8375 (S)	410.8375

(S)—Simplex.

■ 6. Amend § 90.173 by revising paragraph (c) to read as follows.

§ 90.173 Policies governing the assignment of frequencies.

* * * * *

(c) Frequencies assigned to Federal Government radio stations by the National Telecommunications and Information Administration may be authorized under the provisions set forth in § 2.102(c) of this chapter.

[FR Doc. 2018–08790 Filed 5–4–18; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 171026999–8408–02]

RIN 0648–BH36

Fisheries Off West Coast States; Highly Migratory Fisheries; Amendment 4 to Fishery Management Plan for West Coast Highly Migratory Species Fisheries; Revisions to the Biennial Management Cycle

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

ACTION: Final rule.

SUMMARY: Based on recommendations from the Pacific Fishery Mangement Council (Council), NMFS is issuing regulations under the Magnuson-Stevens Fishery Conservation and Management Act (MSA) to implement Amendment 4 to the Fishery Management Plan for U.S. West Coast Highly Migratory Species (HMS FMP). The intent of Amendment 4 is to bring descriptions of the management context for HMS fisheries up to date, to better describe the Council's role in the process of making stock status determinations for highly migratory species (HMS), including the Council's evaluations of the best scientific information available (BSIA), and to change the schedule of the Council's three-meeting biennial management cycle for HMS stocks. This rule updates and amends the descriptions of biennial management cycle activities in the regulations for the HMS FMP to allow the Council to shift the schedule of Council meetings for the consideration of HMS stock status updates and management recommendations in response to instances in which a stock or stocks is determined to be subject to overfishing, overfished, or both. The changes to the Council's biennial management cycle activities and the schedule are intended to better streamline international and domestic management processes for HMS. This rule is administrative in nature and is not expected to affect activities authorized under the FMP or harvest levels of HMS.

DATES: This rule is effective June 6, 2018.

ADDRESSES: Copies of the Amendment 4, the Regulatory Impact Review (RIR) and other supporting documents are available via the Federal eRulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2017–0138, or contact Amber Rhodes, NMFS West Coast Region, 562–980–3231, *Amber.Rhodes@noaa.gov* or Heidi Taylor, NMFS West Coast Region, 562–980–4039, *Heidi.Taylor@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Amber Rhodes, NMFS, 562–980–3231, *Amber.Rhodes@noaa.gov* or Heidi Taylor, NMFS, 562–980–4039, *Heidi.Taylor@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In a January 23, 2018, Notice of Availability (83 FR 3108), NMFS announced that the Council submitted Amendment 4 to the Secretary of Commerce for approval, and requested comments on Amendment 4. The 60-day public comment period ended on March 26, 2018. NMFS approved Amendment 4 to the HMS FMP on April 24, 2018.

On February 27, 2018, NMFS published a proposed rule in the **Federal Register** (83 FR 8414) to implement Amendment 4 by revising regulations at 50 CFR 660.709 contingent upon approval of Amendment 4. The proposed rule contains additional background information on Amendment 4. The 45-day public comment period for the proposed rule closed on April 13, 2018.

Amendment 4 is intended to better align the Council's biennial management cycle for HMS with the timing of international stock assessments and stock status determinations for these species. The changes to the current biennial management cycle included in Amendment 4 and implemented by this rule would allow the Council to streamline domestic and international management activities, such as stock assessment and biological reference point reviews, and to better align schedules to meet statutory timelines in section 304(e) and (i) of the MSA (16 U.S.C. 1854(e) and (i)) for making recommendations for domestic regulations and international measures when stocks are determined to be overfished or subject to overfishing. Additionally, this rule would ensure that the meeting schedule is not codified in regulations, thus allowing the Council to make changes to the schedule for its meetings in the biennial management cycle, consistent with the HMS FMP, without needing to seek a change in the regulatory language. Allowing the Council to make this type of adjustment without seeking a regulatory change improves the efficiency with which future changes to the biennial management cycle can be implemented.

Content of Regulations

This rule amends 50 CFR 660.709 to remove a specific schedule for the Council's biennial management cycle (*i.e.,* during June, September, and November Council meetings) from codified text and replace it with a reference to a biennial management cycle schedule specified in the FMP (*i.e.,* during September, November, and March Council meetings under Amendment 4). Thus, future schedule changes to the Council's biennial management cycle will not require a rulemaking. The rule also provides the Council's Science and Statistical Committee greater discretion over whether to review, and make recommendations on, the estimates in the annual stock assessment and fishery evaluation report.

NMFS did not make any changes in this final rule to the regulatory text of the proposed rule.

Public Comments and Responses

A total of 13 comments were received in response to either the Notice of Availability for the Amendment or the proposed rule. All comments remarked solely on issues beyond the scope of the proposed rule and lacked any specific remarks on NMFS' decision to approve, disapprove, or partially approve the amendment. Because 10 of the comments contained inappropriate content, NMFS made only three of the comments available on the Federal eRulemaking Portal (see **ADDRESSES**).

Classification

The Administrator of the West Coast Region, NMFS, determined that Amendment 4 to the HMS FMP and this final rule are necessary for the conservation and management of U.S. West Coast HMS fisheries and are consistent with the MSA and other applicable laws.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

There are no new collection-of-information requirements associated with this action that are subject to the Paperwork Reduction Act; however, existing collection-of-information requirements associated with the HMS FMP still apply. These requirements have been approved by the Office of Management and Budget (OMB control numbers 0648–0204, 0648–0223, 0648–0361, 0648–0498). Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection-of-information subject to the requirements of the PRA, unless that collection-of-information displays a currently valid OMB control number.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: May 1, 2018.

Alan D. Risenhoover,

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

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

Subpart K—Highly Migratory Fisheries

■ 1. The authority citation for part 660, subpart K, continues to read as follows:

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

■ 2. In § 660.709, remove paragraphs (a)(2) and (a)(3), redesignate paragraph (a)(4) as (a)(2), and revise paragraphs (a)(1) and (d) to read as follows:

§ 660.709 Annual specifications.

(a) * * *

(1) Each year, the HMSMT will deliver a stock assessment and fishery evaluation report to the Council for all HMS with any necessary recommendations for harvest guidelines, quotas or other management measures to protect HMS, including updated maximum sustainable yield (MSY) and optimum yield (OY) estimates based on the best available science. The Council's Scientific and Statistical Committee may review the estimates and make a recommendation on their suitability for management. As described in the fishery management plan, the Council will periodically review these recommendations and decide whether to adopt updated numerical estimates of MSY and OY, which are then submitted as recommendations for NMFS to review as part of the management measures review process.

* * * * *

(d) Irrespective of the normal review process, the Council may propose management action to protect HMS at any time. The Council may adopt a management cycle different from the one described in the fishery management plan provided that such change is made by a majority vote of the Council and a 6-month notice of the change is given.

[FR Doc. 2018–09584 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 88
Monday, May 7, 2018

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0867; Product Identifier 2017–CE–021–AD]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited Airplanes

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

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

SUMMARY: We are revising an earlier proposal for all Viking Air Limited Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes. This proposed airworthiness directive (AD) results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and address an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracking found in the wing rear spar web at the wing station where the flap outboard hinge is attached. This action revises the proposal by issuing an SNPRM that changes the compliance times to more closely match the compliance times in the MCAI. We are proposing this AD to address the unsafe condition on these products. Since these actions may impose an additional burden over those in the notice of proposed rulemaking (NPRM), we are reopening the comment period to allow the public the opportunity to comment on these changes.

DATES: We must receive comments on this proposed AD by June 21, 2018.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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 proposed AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663–8444; fax: (250) 656–0673; email: *technical.support@vikingair.com;* internet: *http://www.vikingair.com/support/service-bulletins.* You may view this service information at the FAA, Policy and Innovation Division, 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 *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0867; 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–0867; Product Identifier 2017–CE–021–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We proposed to amend 14 CFR part 39 with an NPRM for all Viking Air Limited Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes, which was published in the **Federal Register** on September 8, 2017 (82 FR 42489). The NPRM proposed to require actions intended to address the unsafe condition for the products listed above and was based on MCAI originated by another country.

Since the NPRM was issued, we received a comment to change the compliance time for the inspections in the NPRM to be in line with the compliance times stated in Transport Canada, which is the aviation authority for Canada, AD Number CF–2017–17, dated May 18, 2017 (referred to after this as ''the MCAI'').

Comments

We have considered the following comment received on the NPRM.

Request To Change the Compliance Times for the Inspections

Adam Geber stated that the compliance times in the NPRM for the inspections specified in paragraphs (f)(1) and (f)(2) should be changed to match the compliance times stated in the MCAI AD and the related service information.

Adam Geber requested including the 6-month compliance time from the MCAI AD into the proposed AD.

We agree with the commenter. We have changed paragraphs (f)(1) and (f)(2) in this SNPRM from ''within the next 400 hours TIS after the effective date of this AD'' to ''within the next 400 hours TIS after the effective date of this AD or within the next 6 months after the effective date of this AD, whichever occurs first.''

Related Service Information Under 1 CFR Part 51

Viking Air Limited has issued DHC–2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017. The service information describes procedures for inspecting the left-hand and right-hand wing rear spars, the flap/aileron hinge brackets, and the exterior store support bracket for cracks, damage, and discrepancies and specifies repairing or replacing any cracked, damaged, or discrepant parts. 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.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

The change described above expands the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on the proposed AD.

Interim Action

We consider this SNPRM interim action. The inspection report required by this SNPRM allows us to obtain better information into the nature, cause, and extent of the damage to the wing rear spars and flap/aileron hinge arm support brackets and to develop final action to address the unsafe condition. Once final action has been identified, we may consider further rulemaking.

Costs of Compliance

We estimate that this SNPRM will affect 140 products of U.S. registry. We also estimate that it would take about 11 work-hours per product to comply with the basic inspection requirements of this SNPRM. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the basic cost of this proposed AD on U.S. operators to be $130,900, or $935 per product.

In addition, the following is an estimate of possible necessary follow-on replacement actions. We have no way of determining the number of products that may need these actions.

Part No.	Left-hand (LH) or right-hand (RH) wing	Description	Number per airplane	Parts cost	Number of work-hours to replace
C2W123A	Both (one per wing)	Hinge bracket LH inboard (flap)/RH outboard (aileron).	2	$288 for both	12 for both.
C2W124A	Both (one per wing)	Hinge bracket RH inboard (flap)/LH outboard (aileron).	2	$288 for both	12 for both.
C2W143	Both (four per wing)	Hinge bracket, flap and aileron (common part—multiple wing stations (WS)).	8	$271 for all eight	12 for all eight.
C2W143A (Agricultural Option).	Both (one per wing)	Agricultural (optional configuration)—hinge bracket, support arm (IPC PSM 1–2–4 Figure 128, Item 15).	2 (if applies)	$271 for both	12 for both.
C2W63	LH	Inboard spar, rear spar		$277	60.
C2W64	RH	Inboard spar, rear spar		$277	60.
C2W155	Both (one per wing)	Intermediate spar	2	$563 for both	60 for both.
C2W65A	LH	Spar WS 89.16 to WS 170.16	1*	$835	60.
C2W66A	RH	Spar WS 89.16 to WS 170.16	1*	$835	60.
C2W67A	LH	Outboard spar, WS 170.16 to WS 245.75	1*	$835	60.
C2W68A	RH	Outboard spar, WS 170.16 to WS 245.75	1*	$835	60.

*To replace any wing spar section takes 60 work-hours.

To replace all four wing spar sections per wing takes 240 work-hours.

There has been no change in the Cost of Compliance section in this SNPRM.

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 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 control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is 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.

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.

We are 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 aircraft 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs

applicable to small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

Regulatory Findings

We 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) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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 AD:

Viking Air Limited: Docket No. FAA–2017–0867; Product Identifier 2017–CE–021–AD.

(a) Comments Due Date

We must receive comments by June 21, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Viking Air Limited Models DHC–2 Mk. I, DHC–2 Mk. II, and DHC–2 Mk. III airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 57: Wings.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and address an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracking found in the wing rear spar web at the wing station (WS) where the flap outboard hinge is attached. We are issuing this AD to detect and correct cracks in the wing rear spars and the flap/aileron hinge arm support brackets, which could cause these parts to fail. Failure of the wing rear spars and the flap/aileron hinge arm support brackets could result in loss of control.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (5) of this AD:

(1) Within the next 400 hours time-in-service (TIS) after the effective date of this AD or within the next 6 months after the effective date of this AD, whichever occurs first, visually inspect the left-hand and right-hand wing rear spar and flap/aileron hinge arm support brackets following the Accomplishment Instructions of Viking DHC–2 Beaver Service Bulletin Number: V2/0009, Revision A, dated February 10, 2017 (SB V2/0009, Revision A).

(2) For airplanes with agricultural configuration installed (SOO Mod 2/984), within the next 400 hours TIS after the effective date of this AD or within the next 6 months after the effective date of this AD, whichever occurs first, inspect the exterior store support arm bracket at wing station (WS) 101.24 following the Accomplishment Instructions of SB V2/0009, Revision A.

(3) If any discrepancies are found during the inspections required in paragraphs (f)(1) and (2) of this AD, before further flight, repair or replace using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Within 30 days after completing the inspections required in paragraphs (f)(1) and (2) of this AD, using the Operator Reply Form on page 7 of SB V2/0009, Revision A, report the inspection results to Viking Air Limited at the address specified in paragraph (h) of this AD.

(5) As of the effective date of this AD, do not install a wing on any airplane affected by this AD unless it has been inspected as specified in paragraph (f)(1) of this AD and paragraph (f)(2) of this AD, as applicable, and is found free of any discrepancies.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Aziz Ahmed, Aerospace Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada; or Viking Air Limited's Transport Canada Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* For any reporting requirement in this AD, 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 5 minutes 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.

(h) Related Information

Refer to MCAI Transport Canada AD Number CF–2017–17, dated May 18, 2017, for related information. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0867. For service information related to this AD, contact Viking Air Limited Technical Support, 1959 De Havilland Way, Sidney, British Columbia, Canada, V8L 5V5; telephone: (North America) (800) 663–8444; fax: (250) 656–0673; email: *technical.support@vikingair.com;* internet: *http://www.vikingair.com/support/service-bulletins.* You may review copies of the referenced service information at the You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on April 20, 2018.

Melvin Johnson,

Deputy Director, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–08948 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–1051; Airspace Docket No. 17–AGL–21]

RIN 2120–AA66

Proposed Revocation of Class E Airspace; Springfield, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove Class E airspace areas designated as an extension to a Class D surface area at Springfield-Beckley Municipal Airport, Springfield, OH. The FAA is proposing this action as a result of an airspace review, which inadvertently overlooked the removal of the associated Class E airspace extensions when the Class D airspace was removed.

DATES: Comments must be received on or before June 21, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2017–1051; Airspace Docket No. 17–AGL–21, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

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

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

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would remove Class E airspace designated as an extension to a Class D surface area no longer needed at Springfield-Beckley Municipal Airport, Springfield, OH.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2017–1051/Airspace Docket No. 17–AGL–21.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA published a final rule in the **Federal Register** (80 FR 63090, October 19, 2015), removing Class D airspace at Springfield, as a result of the air traffic control tower closure. The FAA did not remove the Class E extensions to the Class D airspace with that final rule.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by removing the Class E airspace extending upward from the surface at Springfield-Beckley Municipal Airport, Springfield, OH. Since the Class D airspace was removed with the closing of the air traffic control tower, the Class E extension airspace is also removed, as the airport no longer qualifies for controlled airspace.

Class E airspace designations are published in paragraph 6004 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR

71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AGL OH E4 Springfield, OH [Removed]

Issued in Fort Worth, Texas, on April 25, 2018.

Christopher L. Southerland,

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

[FR Doc. 2018–09402 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–1187; Airspace Docket No. 17–AGL–25]

RIN 2120–AA66

Proposed Amendment of Class D and Class E Airspace and Proposed Revocation of Class E Airspace; Jackson, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class D airspace, Class E airspace designated as a surface area, and Class E airspace extending upward from 700 feet above the surface, and remove Class E airspace designated as an extension to Class D or Class E surface area at Jackson County Airport-Reynolds Field, Jackson MI. The FAA is proposing this action due to the decommissioning of the Jackson VHF omnidirectional range (VOR) which provided navigation guidance for the instrument procedures to this airport. The VOR is being decommissioned as part of the VOR Minimum Operational Network (MON) Program. The name and the geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database. Additionally, this action would replace the outdated term ''Airport/Facility Directory'' with the term ''Chart Supplement'' in the associated airspace legal descriptions.

DATES: Comments must be received on or before June 21, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2017–1187; Airspace Docket No. 17–AGL–25, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D airspace, Class E airspace designated as a surface area, and Class E airspace extending upward from 700 feet above the surface, and remove Class E airspace designated as an extension to Class D or Class E surface area at Jackson County Airport-Reynolds Field, Jackson MI to support

instrument flight rules (IFR) operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2017–1187; Airspace Docket No. 17–AGL–25.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by:

Modifying the Class D airspace at Jackson County Airport-Reynolds Field, Jackson, MI, by updating the geographic coordinates of the airport to coincide with the FAA's aeronautic database and replacing the outdated term ''Airport/Facility Directory'' with the term ''Chart Supplement'' in the airspace legal description;

Modifying the Class E airspace designated as a surface area at Jackson County Airport-Reynolds Field (formerly Jackson County-Reynolds Field) by removing all airspace extensions from the 4-mile radius in the airspace legal description, updating the name and geographic coordinates of the airport to coincide with the FAA's aeronautical database, and making an editorial change to the airspace legal description replacing ''Airport/Facility Directory'' with the term ''Chart Supplement'';

Removing the Class E airspace designated as an extension to Class D or Class E airspace designated as a surface area at Jackson County-Reynolds Field, MI, as it is no longer required; and

Modifying the Class E airspace area extending upward from 700 feet above the surface to within a 6.5-mile radius (decreased from a 7-mile radius) of Jackson County Airport-Reynolds Field (formerly Jackson County-Reynolds Field), removing the Jackson VOR/DME from the airspace legal description, and updating the name and geographic coordinates to coincide with the FAA's aeronautical database.

Airspace reconfiguration is necessary due to the decommissioning of the Jackson VOR, which provided navigation guidance for the instrument procedures to this airport, as part of the VOR MON Program and to bring the airspace in compliance with FAA Order 7400.2L, Procedures for Handling Airspace Matters. This action would enhance safety and the management of IFR operations at this airport.

Class D and E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting

Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL MI D Jackson, MI [Amended]

Jackson County Airport-Reynolds Field, MI
(Lat. 42°15′38″ N, long. 84°27′44″ W)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4-mile radius of Jackson County Airport-Reynolds Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

AGL MI E2 Jackson, MI [Amended]

Jackson County Airport-Reynolds Field, MI
(Lat. 42°15′38″ N, long. 84°27′44″ W)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4-mile radius of Jackson County Airport-Reynolds Field. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designates as an Extension to Class D and Class E Surface Areas.

* * * * *

AGL MI E4 Jackson, MI [Removed]

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

* * * * *

AGL MI E5 Jackson, MI [Amended]

Jackson County Airport-Reynolds Field, MI
(Lat. 42°15′38″ N, long. 84°27′44″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Jackson County Airport-Reynolds Field.

Issued in Fort Worth, Texas, on April 30, 2018.

Christopher L. Southerland,

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

[FR Doc. 2018–09560 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2018–0003]

RIN 1218–AB76

Revising the Beryllium Standard for General Industry

AGENCY: Occupational Safety and Health Administration (OSHA); Department of Labor.

ACTION: Proposed rule.

SUMMARY: On January 9, 2017, the Occupational Safety and Health Administration (OSHA) issued a final rule adopting a comprehensive general industry standard for exposure to beryllium and beryllium compounds. In this proposed rule, OSHA is proposing to adopt a number of clarifying amendments to address the application of the standard to materials containing trace amounts of beryllium. OSHA believes this proposal will maintain safety and health protections for workers while reducing the burden to employers of complying with the current rule.

DATES: Comments to this proposal, hearing requests, and other information must be submitted (transmitted, postmarked, or delivered) by June 6, 2018. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: The public can submit comments, hearing requests, and other material, identified by Docket No. OSHA–2018–0003, using any of the following methods:

Electronically: Submit comments and attachments, as well as hearing requests and other information, electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments. Note that this docket may include several different **Federal Register** notices involving active rulemakings, so it is extremely important to select the correct notice or its ID number when submitting comments for this rulemaking. After accessing ''all documents and comments'' in the docket (OSHA–2018–0003), check the ''proposed rule'' box in the column headed ''Document Type,'' find the document posted on the date of publication of this document, and click the ''Submit a Comment'' link. Additional instructions for submitting comments are available from the *http://www.regulations.gov* homepage.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693–1648. OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (*e.g.,* studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Docket No. OSHA–2018–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. These attachments must clearly identify the sender's name, the date, the subject, and the docket number (OSHA–2018–0003) so that the Docket Office can attach them to the appropriate document.

Regular mail, express delivery, hand delivery, and messenger (courier) service: Submit comments and any additional material to the OSHA Docket Office, Docket No. OSHA–2018–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service. The Docket Office will accept deliveries (express delivery, hand delivery, messenger service) during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the Agency's name, the title of the rulemaking (Beryllium Standard: Notice of Proposed Rulemaking), and the docket number (OSHA–2018–0003). OSHA will place comments and other material, including any personal information, in the public docket without revision, and the comments and other material will be available online at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others), such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the above address. The electronic docket for this proposed rule established at *http://www.regulations.gov* contains most of

the documents in the docket. However, some information (*e.g.,* copyrighted material) is not available publicly to read or download through this website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Mr. Frank Meilinger, OSHA Office of Communications, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3647, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information and technical inquiries: William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3718, 200 Constitution Avenue NW, Washington, DC 20210; telephone (202) 693–1950.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

On January 9, 2017, OSHA published its final rule Occupational Exposure to Beryllium and Beryllium Compounds in the **Federal Register** (82 FR 2470). OSHA concluded that employees exposed to beryllium and beryllium compounds at the preceding permissible exposure limits (PELs) were at significant risk of material impairment of health, specifically chronic beryllium disease and lung cancer. OSHA concluded that the new 8-hour time-weighted average (TWA) PEL of 0.2 μg/m^3 reduced this significant risk to the maximum extent feasible. Based on information submitted to the record, in the final rule OSHA issued three separate standards—general industry, shipyards, and construction. In addition to the revised PEL, the final rule established a new short-term exposure limit (STEL) of 2.0 μg/m^3 over a 15-minute sampling period and an action level of 0.1 μg/m^3 as an 8-hour TWA, along with a number of ancillary provisions intended to provide additional protections to employees, such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping similar to those found in other OSHA health standards.

This proposal would amend the text of the beryllium standard for general industry to clarify OSHA's intent with respect to certain terms in the standard, including the definition of Beryllium Work Area (BWA), the definition of emergency, and the meaning of the terms dermal contact and beryllium contamination. It also would clarify OSHA's intent with respect to provisions for disposal and recycling and with respect to provisions that the Agency intends to apply only where skin can be exposed to materials containing at least 0.1% beryllium by weight.

This proposed rule is expected to be an Executive Order (E.O.) 13771 deregulatory action. Details on OSHA's cost/cost savings estimates for this proposed rule can be found in the rule's preliminary economic analysis. OSHA has estimated that, at a 3 percent discount rate over 10 years, there are net annual cost savings of $0.36 million per year for this proposed rule; at a discount rate of 7 percent there are net annual cost savings of $0.37 million per year. When the Department uses a perpetual time horizon, the annualized cost savings of the proposed rule is $0.37 million with 7 percent discounting. While the 2017 Beryllium Final Rule went into effect on May 20, 2017, compliance obligations do not begin until May 11, 2018.

OSHA has preliminarily determined that the standard as modified by this rulemaking would provide equivalent protection to the standard as promulgated. Accordingly, while this rulemaking is pending, OSHA will consider compliance with the standard as modified by this proposal to be a de minimis condition and will not issue a citation or penalty to employers in compliance with the proposed standard, in accordance with the Agency's de minimis citation policy.

II. Consideration of Comments

OSHA requests comment on all issues related to this proposed rule. As discussed more fully below, this proposed rule is the companion document to a direct final rule published in the ''Rules'' section of this issue of the **Federal Register**. If OSHA receives no significant adverse comment on the proposal or direct final rule, OSHA will publish a **Federal Register** document confirming the effective date of the direct final rule and withdrawing this companion Notice of Proposed Rulemaking (NPRM). Such confirmation may include minor stylistic or technical changes to the direct final rule. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of the direct final rule as the date of promulgation. If, however, OSHA receives a significant adverse comment on the direct final rule or proposal, the Agency will publish a timely withdrawal of the direct final rule and proceed with the proposed rule, which addresses the same revisions to the beryllium standard for general industry.

III. Direct Final Rulemaking

As noted above, in addition to publishing this NPRM, OSHA is concurrently publishing a companion direct final rule (DFR) in the **Federal Register**. In direct final rulemaking, an agency publishes a DFR in the **Federal Register**, with a statement that the rule will go into effect unless the agency receives significant adverse comment within a specified period. The agency may publish an identical concurrent NPRM. If the agency receives no significant adverse comment in response to the DFR, the rule goes into effect. OSHA typically confirms the effective date of a DFR through a separate **Federal Register** document. If the agency receives a significant adverse comment, the agency withdraws the DFR and treats such comment as a response to the NPRM. An agency typically uses direct final rulemaking when an agency anticipates that a rule will not be controversial.

For purposes of the DFR, a significant adverse comment is one that explains why the amendments to OSHA's beryllium standard would be inappropriate. In determining whether a comment necessitates withdrawal of the DFR, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. OSHA will not consider a comment recommending an additional amendment to this rule to be a significant adverse comment unless the comment states why the DFR would be ineffective without the addition.

The comment period for this NPRM runs concurrently with that of the DFR. OSHA will treat comments received on the NPRM as comments also regarding the companion DFR. Similarly, OSHA will consider significant adverse comment submitted to the companion DFR as comment to the NPRM. Therefore, if OSHA receives a

significant adverse comment on either the DFR or this NPRM, it will withdraw the companion DFR and proceed with the NPRM. In the event OSHA withdraws the DFR because of significant adverse comment, OSHA will consider all timely comments received in response to the DFR when it continues with the NPRM. After carefully considering all comments to the DFR and the NPRM, OSHA will decide whether to publish a new final rule.

OSHA determined that the subject of this rulemaking is suitable for direct final rulemaking. This proposed amendment to the standard is clarifying in nature and does not adversely impact the safety or health of employees. The amended standard would clarify OSHA's intent regarding certain terms in the standard, including the definition of Beryllium Work Area (BWA), the definition of emergency, and the meaning of the terms dermal contact and beryllium contamination. It also would clarify OSHA's intent with respect to provisions for disposal and recycling and with respect to provisions that the Agency intends to apply only where skin can be exposed to materials containing at least 0.1% beryllium by weight. The revisions would not impose any new costs or duties. For these reasons, OSHA does not anticipate objections from the public to this rulemaking action.

IV. Discussion of Proposed Changes

On January 9, 2017, OSHA adopted comprehensive standards addressing exposure to beryllium and beryllium compounds in general industry, construction, and shipyards. 82 FR 2470. Beryllium ''occurs naturally in rocks, soil, coal, and volcanic dust,'' but can cause harm to workers through exposure in the workplace. 80 FR 47579. OSHA has thus set a general industry exposure limit for beryllium and beryllium compounds since 1971, modified most recently in 2017. *See* 80 FR 47578–47579; 82 FR 2471. This proposal would amend that 2017 general industry beryllium standard (codified at 29 CFR 1910.1024) to clarify its applicability to materials containing trace amounts of beryllium and to make related changes. This proposal would not affect the construction and shipyard standards, which are being addressed in a separate rulemaking. See 82 FR 29182.

During the last rulemaking, OSHA addressed the issue of trace amounts of beryllium. In its notice of proposed rulemaking, OSHA proposed to exempt from its beryllium standard materials containing less than 0.1% beryllium by weight on the premise that workers in exempted industries are not exposed at levels of concern, 80 FR 47775, but noted evidence of high airborne exposures in some of those industries, in particular the primary aluminum production and coal-fired power generation industries. 80 FR 47776. Therefore, OSHA proposed for comment several regulatory alternatives, including an alternative that would ''expand the scope of the proposed standard to also include all operations in general industry where beryllium exists only as a trace contaminant.'' 80 FR 47730. After receiving comment, OSHA adopted in the final rule an alternative limiting the exemption for materials containing less than 0.1% beryllium by weight to where the employer has objective data demonstrating that employee exposure to airborne beryllium will remain below the action level (AL) of 0.1 $\mu g/m^3$, measured as an 8-hour TWA, under any foreseeable conditions. 29 CFR 1910.1024(a)(2). In doing so, OSHA noted that the AL exception ensured that workers with airborne exposures of concern were covered by the standard:

> OSHA agrees with the many commenters and testimony expressing concern that materials containing trace amounts of beryllium (less than 0.1 percent by weight) can result in hazardous [airborne] exposures to beryllium. We disagree, however, with those who supported completely eliminating the exemption because this could have unintended consequences of expanding the scope to cover minute amounts of naturally occurring beryllium (Ex 1756 Tr. 55). Instead, we believe that alternative #1b—essentially as proposed by Materion and USW [United Steelworkers] and acknowledging that workers can have significant [airborne] beryllium exposures even with materials containing less than 0.1%—is the most appropriate approach. Therefore, in the final standard, it is exempting from the standard's application materials containing less than 0.1% beryllium by weight only where the employer has objective data demonstrating that employee [airborne] exposure to beryllium will remain below the action level as an 8-hour TWA under any foreseeable conditions. 82 FR 2643.

As the regulatory history makes clear, OSHA intended to protect employees working with trace beryllium only when it caused airborne exposures of concern. OSHA did not intend for provisions aimed at protecting workers from the effects of dermal contact to apply in the case of materials containing only trace amounts of beryllium. Since the publication of the final rule, however, stakeholders have suggested that an unintended consequence of the final rule's revision of the trace exemption is that provisions designed to protect workers from dermal contact with beryllium-contaminated material could be read as applying to materials with only trace amounts of beryllium.

This proposal would adjust the regulatory text of the general industry beryllium standard to clarify that OSHA does not intend for requirements that primarily address dermal contact to apply in processes, operations, or areas involving only materials containing less than 0.1% beryllium by weight. These proposed clarifications would be made through changes to the definition of beryllium work area; the addition of definitions of dermal contact, beryllium-contaminated, and contaminated with beryllium; clarifications of certain hygiene provisions with respect to beryllium contamination; and the clarifications to provisions for disposal and recycling. In addition, because under these changes it is possible to have a regulated area that is not a beryllium work area, this proposal would make changes to certain housekeeping provisions to ensure they apply in all regulated areas. Finally, this proposal also includes a change to the definition of ''emergency'', adding detail to the definition so as to clarify the nature of the circumstances OSHA intends to be considered an emergency for the purposes of the standard.

Definition of beryllium work area. Paragraph (b) of the beryllium standard published in January 2017 defined a beryllium work area as any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. This proposal would amend the definition as follows: ''Beryllium work area means any work area: (1) Containing a process or operation that can release beryllium and that involves materials that contain at least 0.1% beryllium by weight; and (2) where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.'' This change would clarify OSHA's intent that many of the provisions associated with beryllium work areas should only apply to areas where there are processes or operations involving materials at least 0.1% beryllium by weight.

Specifically, this proposed change to the beryllium work area definition would clarify OSHA's intent that the following provisions associated with beryllium work areas do not apply where processes and operations involve only materials containing trace amounts of beryllium (less than 0.1% beryllium by weight): Establishing and

demarcating beryllium work areas (paragraphs (e)(1)(i) and (e)(2)(i)); including procedures for minimizing cross-contamination within (paragraph (f)(1)(i)(D)) or minimizing migration of beryllium out of (paragraph (f)(1)(i)(F)) such areas in the written exposure control plan; ensuring that at least one engineering or process control is in place to reduce beryllium exposure where airborne beryllium levels meet or exceed the AL (revised paragraph (f)(2)(ii)).[1] Additionally, for areas where beryllium is only present in materials at concentrations of less than 0.1% beryllium by weight, unless that area is also a regulated area, employers are not required to ensure that all surfaces in such areas are as free as practicable of beryllium (paragraph (j)(1)(i)); ensure that all surfaces in such areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure (paragraph (j)(2)(i)); or prohibit dry sweeping or brushing for cleaning surfaces in such areas (paragraph (j)(2)(ii)).

This proposal also includes conforming changes to maintain the January 2017 rule's requirements for housekeeping in regulated areas. Because all regulated areas were also beryllium work areas under the January 2017 beryllium standard, OSHA did not specify whether requirements for beryllium work areas should also apply in regulated areas (areas in which airborne beryllium exposure meets or exceeds the TWA PEL or STEL). This proposal's clarification to the definition of beryllium work area, however, means that it is possible for a work area to be a regulated area, but not a beryllium work area. This would occur when processes that involve only materials containing less than 0.1% beryllium by weight nevertheless create airborne beryllium exposures at or above the TWA PEL or STEL. 82 FR 2583.

It is thus important to clarify that housekeeping (paragraph (j)) requirements continue to apply in regulated areas, even if the processes or operations in these areas involve materials with only trace beryllium. Operations or processes involving trace beryllium materials must generate extremely high dust levels in order to exceed the TWA PEL or STEL. Following the housekeeping methods required by paragraph (j) will help to protect workers against resuspension of surface beryllium accumulations from extremely dusty operations and limit workers' airborne exposure to beryllium.

The proposal accordingly would amend paragraphs (j)(1)(i), (j)(2)(i), and (j)(2)(ii) to state explicitly that they apply to regulated areas, as follows. Paragraph (j)(1)(i), as amended, would state that ''[t]he employer must maintain all surfaces in beryllium work areas and regulated areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard.'' Paragraph (j)(2)(i), as amended, would state that ''[t]he employer must ensure that surfaces in beryllium work areas and regulated areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.'' Paragraph (j)(2)(ii), as amended, would state that ''[t]he employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas or regulated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.''

This proposal would also make conforming changes to the engineering controls requirements to ensure that the hierarchy of controls continues to apply in all regulated areas. Paragraph (f)(2) of the January 2017 beryllium standard provided that, if airborne exposures still exceed the PEL or STEL after implementing at least one control for each operation in a beryllium work area that releases airborne beryllium, the employer must implement additional or enhanced engineering and work practice controls to reduce airborne exposure to or below the limit exceeded. OSHA intended this provision to apply to all operations within the scope of the standard that can release airborne beryllium. 82 FR 2671–72. Because, under these proposed revisions, not all regulated areas would be beryllium work areas, this proposal would rearrange the regulatory text of paragraph (f)(2) to make clear that the hierarchy of controls will continue to apply in regulated areas that are not beryllium work areas.

Definitions related to beryllium contamination. To further clarify OSHA's intent that the standard's requirements aimed at reducing the effect of dermal contact with beryllium should not apply to areas where there are no processes or operations involving materials containing at least 0.1% beryllium by weight, this proposal would define ''beryllium-contaminated or contaminated with beryllium'' and add those terms to certain provisions in the standard. This proposal would define those terms as follows: ''Contaminated with beryllium and beryllium-contaminated mean contaminated with dust, fumes, mists, or solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight.'' This proposal would add the terms to certain provisions in the standard's requirements for hygiene areas and disposal and recycling.

The use of this proposed definition accordingly would clarify OSHA's intent that the following provisions, which apply where clothing, hair, skin, or work surfaces are beryllium-contaminated, do not apply where the contaminating material contains less than 0.1% beryllium by weight: Paragraph (h)(2)(i) and paragraph (h)(2)(ii), which require the employer to ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the appropriate time and as specified in the written exposure control plan required by paragraph (f)(1); and paragraph (h)(2)(iii) and paragraph (h)(2)(iv), which require the employer to ensure that measures to prevent cross contamination between beryllium-contaminated personal protective clothing and equipment and street clothing are observed and that beryllium-contaminated personal protective clothing and equipment are not removed from the workplace. This proposal would also amends paragraph (h)(3)(ii), which requires the employer to ensure that beryllium is properly removed from PPE, by adding the term ''beryllium-contaminated'' so that this requirement would apply only where the contaminating material contains at least 0.1% beryllium by weight. The amended paragraph (h)(3)(ii) would read as follows: ''The employer must ensure that beryllium is not removed from beryllium-contaminated personal protective clothing and equipment by blowing, shaking, or any other means that disperses beryllium into the air.''

Similarly, this proposal's inclusion of the term ''contaminated with beryllium'' in (i)(3)(i)(B) and (i)(3)(ii)(B) clarifies OSHA's intent that those provisions,

[1] As explained in the preamble to the January 2017 rule, in industries that process or handle materials with only trace amounts of beryllium and that encounter exposures to beryllium above the action level, the PEL would ''be exceeded only during operations that generate [an] excessive amount of visible airborne dust.'' 82 FR 2583. OSHA therefore expects that if exposures in such a facility are below the PEL but above the AL, there is already at least one engineering or process control in place, so this requirement had no effect on primary aluminum production or coal-fired utilities. The 2017 FEA explained that this provision would only require additional controls in two job categories in two application groups, neither of which are in primary aluminum production or coal-fired utilities. (Document ID OSHA–H005C–2006–0870–2042, p. V–12).

which require employers to provide and ensure use of showers where employees' hair or body parts other than hands, face, and neck can reasonably be expected to become contaminated with beryllium, would not apply where the contaminating material contains less than 0.1% beryllium by weight.

The proposed adoption of the definition of ''beryllium-contaminated'' would further clarify the application of certain requirements that are meant to minimize re-entrainment of airborne beryllium and reduce the effect of dermal contact with beryllium. Specifically, it would clarify that paragraph (j)(2)(iii), which prohibits the use of compressed air for cleaning beryllium-contaminated surfaces except where used in conjunction with an appropriate ventilation system, and paragraph (j)(2)(iv), which requires the use of respiratory protection and PPE in accordance with paragraphs (g) and (h) of the standard when dry sweeping, brushing, or compressed air are used to clean beryllium-contaminated surfaces, do not apply where the contaminating material contains less than 0.1% beryllium by weight. OSHA does not expect the additional airborne exposure from dry brushing, sweeping, or using compressed air to significantly increase the levels of airborne exposure outside regulated areas when working with trace beryllium. This is because for trace beryllium to generate airborne exposures of concern, excessive amounts of dust would need to be generated, and this would not happen outside of regulated areas.

This proposal would also add the term ''beryllium-contaminated'' to certain requirements pertaining to eating and drinking areas to clarify that hygiene requirements in these areas apply only where materials containing more than 0.1% beryllium by weight may contaminate such areas. Paragraph (i)(4)(i), as amended by this proposal, would state that wherever the employer allows employees to consume food or beverages at a worksite where beryllium is present, the employer must ensure that ''[b]eryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium.'' Paragraph (i)(4)(ii), as amended by this proposal, would require employers to ensure that ''[n]o employees enter any eating or drinking area with beryllium-contaminated personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body.''

Definition of dermal contact with beryllium. To clarify OSHA's intent that requirements of the standard associated with dermal contact with beryllium should not apply to areas where there are no processes or operations involving materials at least 0.1% beryllium by weight, this proposal would also add a definition for dermal contact with beryllium. This new definition would provide: ''Dermal contact with beryllium means skin exposure to: (1) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight; (2) solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight; or (3) dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight.'' Accordingly, the proposed definition would clarify that paragraph (h)(1)(ii), which requires an employer to provide and ensure the use of personal protective clothing and equipment where there is a reasonable expectation of dermal contact with beryllium, applies only where contact may occur with materials containing at least 0.1% beryllium by weight. This definition would also clarify that the requirements related to dermal contact in the written exposure control plan, washing facilities, medical examinations, and training provisions only apply where contact may occur with materials containing at least 0.1% beryllium by weight.

Definition of emergency. This proposal also would clarify the definition of ''emergency'' in paragraph (b) of the beryllium standard published in January 2017. That paragraph defined an emergency as ''any uncontrolled release of airborne beryllium.'' This proposal would amend the definition as follows: ''Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an uncontrolled and unintended release of airborne beryllium that presents a significant hazard.'' This change would clarify the circumstances under which the provisions associated with emergencies should apply, including the requirements that employers provide and ensure employee use of respirators and that employers provide medical surveillance to employees exposed in an emergency. This proposed change is consistent with OSHA's intent as explained in the preamble to the 2017 final rule. 82 FR 2690 (''An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes.''). These examples show OSHA's intent to define an ''emergency'' as something unintended as well as uncontrolled, and including the examples in the new definition make that clear. It is also consistent with other OSHA standards, such as methylenedianiline (1910.1050), vinyl chloride (1910.1017), acrylonitrile (1910.1045), benzene (1910.1028), and ethylene oxide (1910.1047).

Disposal and recycling. Finally, this proposal would clarify the application of the disposal and recycling provisions. Paragraph (j)(3) of the beryllium standard published in January 2017 required employers to ensure that materials designated for disposal that contain or are contaminated with beryllium are disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of the standard. It also required that materials designated for recycling which contain or are contaminated with beryllium are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of the standard, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of the standard. These provisions were designed to protect workers from dermal contact with beryllium dust generated during processing, where there is a risk of beryllium sensitization. See 82 FR 2694, 2695. This proposal accordingly would limit those requirements to ''materials that contain beryllium in concentrations of 0.1 percent by weight or more or are contaminated with beryllium,'' consistent with OSHA's intention that provisions aimed at protecting workers from the effects of dermal contact do not apply in the case of materials containing only trace amounts of beryllium The hazard communication standard would continue to apply according to its terms. See 29 CFR 1910.1200.

V. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970) (''OSH Act''; 29 U.S.C. 651 *et seq.*) is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 655(b), 658. A safety or health standard is a standard that ''requires conditions, or the

adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate when a significant risk of material harm exists in the workplace and the standard would substantially reduce or eliminate that workplace risk. See *Industrial Union Dept., AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 641–42 (1980) (plurality opinion).

OSHA need not make additional findings on risk for this proposal. As discussed above, this proposal would not diminish the employee protections put into place by the standard being amended. And because OSHA previously determined that the beryllium standard substantially reduces a significant risk (82 FR 2545–52), it is unnecessary for the Agency to make additional findings on risk for the minor changes and clarifications proposed by this rulemaking. See, *e.g., Public Citizen Health Research Group* v. *Tyson,* 796 F.2d 1479, 1502 n.16 (DC Cir. 1986) (rejecting the argument that OSHA must ''find that each and every aspect of its standard eliminates a significant risk.'').

OSHA has determined that these minor changes and clarifications are technologically and economically feasible. All OSHA standards must be both technologically and economically feasible. See *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1264 (DC Cir. 1980) (''*Lead I*''). The Supreme Court has defined feasibility as ''capable of being done.'' *Am. Textile Mfrs. Inst.* v. *Donovan,* 452 U.S. 490, 509–10 (1981) (''*Cotton Dust*''). Courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility, ''within the limits of the best available evidence . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most of its operations.'' *Lead I,* 647 F.2d at 1272. With respect to economic feasibility, courts have held that ''a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry.'' *Id.* at 1265 (internal quotation marks and citations omitted). In the final economic analysis (FEA) for the 2017 beryllium rule, OSHA concluded that the rule was economically and technologically feasible. OSHA has preliminarily determined that this proposal is also economically and technologically feasible, because it does not impose any new requirements or costs.

VI. Preliminary Economic Analysis and Regulatory Flexibility Act Certification

Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)) require that OSHA estimate the benefits, costs, and net benefits of regulations, and analyze the impacts of certain rules that OSHA promulgates. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This proposal is not an ''economically significant regulatory action'' under Executive Order 12866, or a ''major rule'' under the Congressional Review Act (5 U.S.C. 801 *et seq.*), and its impacts do not trigger the analytical requirements of UMRA. Neither the benefits nor the costs of this proposal would exceed $100 million in any given year. This proposal would, however, result in a net cost savings for employers in primary aluminum production and coal-fired utilities, which are the only industries in General Industry covered by the 2017 Beryllium Final Rule that OSHA identified with operations involving materials containing only trace beryllium (less than 0.1% beryllium by weight).

Several calculations illustrate the expected cost savings. At a discount rate of 3 percent, this proposal would yield annualized cost savings of $0.36 million per year for 10 years. At a discount rate of 7 percent, this proposal would yield an annualized cost savings of $0.37 million per year for 10 years. These net cost savings amount to approximately 0.6 percent of the original estimated cost of the 2017 Beryllium Final Rule for General Industry at discount rates of either 3 or 7 percent; to approximately 5.3 percent of the original estimated cost of the 2017 Beryllium Final Rule for primary aluminum production and coal-fired utilities only at a discount rate of 3 percent and 5.2 percent of the original estimated cost of the 2017 Beryllium Final Rule for primary aluminum production and coal-fired utilities only at a discount rate of 7 percent.[2] Under a perpetual time horizon, the annualized cost savings of this proposal is $0.37 million at a discount rate of 7 percent.

[2] The original estimated cost of the 2017 beryllium final rule for General Industry, and separately for primary aluminum production and coal-fired utilities, was updated to 2017 dollars and additionally adjusted and corrected, as subsequently explained in the text.

1. Changes to the Baseline: Updating to 2017 Dollars and Removing Familiarization Costs

Because baseline costs typically reflect the costs of compliance *without* the changes set forth in an agency's action—in this case, the proposal—OSHA has revised the baseline costs, as displayed in the FEA in support of the beryllium standard of January 9, 2017, in two ways. First, OSHA updated the projected costs for general industry contained in the FEA that accompanied the rule from 2015 to 2017 dollars, using the latest Occupational Employment Statistics (OES) wage data (for 2016) and inflating them to 2017 dollars. Second, OSHA excluded certain familiarization costs, included in the cost estimates developed in the beryllium FEA for the 2017 Beryllium Final Rule, because OSHA expects that those costs have already been incurred by affected employers. Thus, the baseline costs for this Preliminary Economic Analysis (PEA) are the projected costs from the 2017 FEA, updated to 2017 dollars, less familiarization costs in the 2017 beryllium final rule (but including some new familiarization costs for employers to become familiar with the revised provisions). Throughout this analysis of costs and cost savings, the context is limited to employers in primary aluminum production and coal-fired utilities.

2. Discussion of Overhead Costs

As in the 2017 FEA, OSHA has not accounted for overhead labor costs in its analysis of the cost savings for this proposal due to concerns about consistency. There are several ways to look at the cost elements that fit the definition of overhead, and there is a range of overhead estimates currently used within the federal government—for example, the Environmental Protection Agency has used 17 percent,[3] and government contractors have been reported to use an average of 77 percent.[4] Some overhead costs, such as

[3] See Grant Thornton LLP. 2015 Government Contractor Survey (Document ID OSHA–H005C–2006–0870–2153). The application of this overhead rate was based on an approach used by the Environmental Protection Agency, as described in EPA's ''Wage Rates for Economic Analyses of the Toxics Release Inventory Program,'' June 10, 2002. This analysis itself was based on a survey of several large chemical manufacturing plants: Heiden Associates, Final Report: A Study of Industry Compliance Costs Under the Final Comprehensive Assessment Information Rule, Prepared for the Chemical Manufacturers Association, December 14, 1989.

[4] For further examples of overhead cost estimates, please see the Employee Benefits Security Administration's guidance at *https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-*

advertising and marketing, may be more closely correlated with output than with labor. Other overhead costs vary with the number of new employees. For example, rent or payroll processing costs may change little with the addition of 1 employee in a 500-employee firm, but may change substantially with the addition of 100 employees. If an employer is able to rearrange current employees' duties to implement a rule, then the marginal share of overhead costs, such as rent, insurance, and major office equipment (*e.g.,* computers, printers, copiers) would be very difficult to measure with accuracy.

If OSHA had included an overhead rate when estimating the marginal cost of labor, without further analyzing an appropriate quantitative adjustment, and adopted for these purposes an overhead rate of 17 percent on base wages, the cost savings of this proposal would increase to approximately $0.39 million per year, at discount rates of either 3 percent or 7 percent.[5] The addition of 17 percent overhead on base wages would therefore increase cost savings by approximately 7 percent above the primary estimate at either discount rate.

3. Cost Impact of the Changes to the Standard

OSHA preliminarily estimates a net cost savings from this proposal for employers at primary aluminum production and coal-fired utilities, which again are the only two industries identified in the 2017 FEA as having costs associated with exposure to trace beryllium materials.[6] Annualizing the present value of net cost savings over ten years, the result is an annualized net cost savings of $0.36 million per year at a discount rate of 3 percent, or $0.37 million per year at a discount rate of 7 percent. When the Department uses a perpetual time horizon, the annualized net cost savings of this proposal is $0.37 million at a discount rate of 7 percent.

The undiscounted cost savings by provision and year are presented below in Table 1, and the cost savings by provision and discount rate are shown below in Tables 2 and 3. As described elsewhere in this document, the cost savings described in this PEA reflect savings only for provisions covered by the changes in this proposal as well as added familiarization costs. OSHA estimated no cost savings for the PEL, respiratory protection, exposure assessment, regulated areas, medical surveillance, medical removal protection, written exposure control plan, or training provisions because the proposal would make no changes of substance to those provisions.

a. Beryllium work areas. OSHA is proposing to limit the definition of ''beryllium work area'' to any work area containing a process or operation ''that involves materials that contain at least 0.1% beryllium by weight. . . .'' OSHA has preliminarily determined that affected establishments in primary aluminum production and coal-fired utilities would thus no longer need to designate and demarcate beryllium work areas because their materials would not meet that threshold outside of the ''regulated areas'' in primary aluminum production where employee exposures to airborne beryllium would exceed the PEL. In its previous economic analysis, OSHA had estimated that each of the establishments in these categories required beryllium work areas in addition to ''regulated areas,'' which were costed separately. The removal of these beryllium work area designations results in an annualized cost savings of $12,913 using a 3 percent discount rate and $15,682 using a 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

b. Protective work clothing and equipment. OSHA is recognizing no cost savings in this proposal for the elimination of PPE requirements associated with dermal contact in coal-fired utilities. In its 2017 FEA, OSHA listed the PPE compliance rate for utility workers at coal-fired utilities at 75 percent and therefore estimated PPE costs for the residual 25 percent of utility workers in the industry (where airborne exposures exceed the PEL or STEL or where there is dermal contact with beryllium). But upon further review, OSHA has preliminarily determined that it should not have included those costs because affected employers in coal-fired utilities were already required to wear PPE under 29 CFR 1910.1018(j) to prevent skin and eye irritation from exposure to trace inorganic arsenic found in coal ash. As OSHA noted in its technological feasibility analysis, inorganic arsenic is often found in coal fly ash in ''concentrations 10 to 1,000 times greater than beryllium,'' fly ash is the primary source of beryllium exposure for employees in coal-fired utilities, and employers in this application group indicated that they were already following a majority of the provisions of the rule to comply with OSHA requirements for other hazardous substances, such as arsenic (p. IV–652). Thus, in all of the areas within a facility in which employees are likely to be exposed to beryllium, they are also likely to be exposed to concentrations of arsenic significantly high so as to trigger the arsenic PPE requirements. Accordingly, coal-fired utility compliance rates with the PPE requirement for affected workers should have been 100 percent in the prior FEA, and no costs for PPE for these workers should have been included in OSHA's cost estimates. Because OSHA should not have included new beryllium PPE costs for this group, OSHA is recognizing no cost savings in this proposal for the elimination of PPE requirements associated with dermal contact in coal-fired utilities.

There are, however, some small PPE cost savings for primary aluminum production. The January 2017 rule requires employers to provide PPE in two situations: (1) Where airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; and (2) where there is a reasonable expectation of dermal contact with beryllium. 29 CFR 1910.1024(h)(1). It is the second of these two situations which OSHA believes will trigger cost savings. Because this proposal would clarify that ''dermal contact with beryllium'' does not include contact with beryllium in concentrations less than 0.1% beryllium by weight, gloves and other PPE requirements would be triggered by a reasonable expectation of dermal contact only with materials containing more than 0.1% beryllium by weight. In primary aluminum production, there is no dermal contact with materials containing beryllium above this threshold. As a result, the Agency has preliminarily determined that in primary aluminum production, additional PPE is only necessary for workers exposed over the PEL. This change results in an annualized cost savings for employers in primary aluminum production of $35,023 using

inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf.

[5] OSHA used an overhead rate of 17 percent on base wages in a sensitivity analysis in the FEA (OSHA–2010–0034–4247, p. VII–65) in support of the March 25, 2016 final respirable crystalline silica standards (81 FR 16286) and in the PEA in support of the June 27, 2017 proposed beryllium standards in construction and shipyard sectors (82 FR 29201).

[6] As noted in Section IV of this preamble, coverage of dermal contact with trace beryllium materials was an unintended consequence of OSHA's decision to cover airborne exposures to beryllium above the action level caused by operations that generate excessive amounts of dust from trace beryllium materials. Likewise, in the 2017 FEA supporting OSHA's Beryllium Final Rule, through an oversight, OSHA made no distinction between trace and non-trace beryllium materials when determining the cost of requirements triggered by dermal contact with beryllium. The cost savings generated by this PEA are a result of correcting these oversights.

a 3 or 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

c. Hygiene areas and practices. The proposed adoption of a definition for ''contaminated with beryllium'' would also reduce the costs of complying with the Hygiene Areas and Practices provision in primary aluminum production (the costs for coal-fired utilities would not be affected). The 2017 Final Beryllium Rule requires employers to provide showers where both of two conditions are met:

(A) Airborne exposure exceeds, or can reasonably be expected to exceed, the TWA PEL or STEL; and

(B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck.

29 CFR 1910.1024(i)(3)(i). By proposing to revise (B) to incorporate the newly defined term ''contaminated with beryllium,'' the condition in paragraph (B) would not be met in primary aluminum production because no employees in this application group can reasonably be expected to become ''contaminated with beryllium.'' Thus, the beryllium standard would not require employers in this application group to provide showers. Similarly, employers need not provide the estimated lower-cost alternative of head coverings, discussed in the 2017 FEA.[7] Removing the cost of head coverings for workers in this application group results in an annualized cost savings for employers in primary aluminum production of $415 using a 3 or 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3.

d. Housekeeping. Similar to the above discussion about PPE in coal-fired utilities, OSHA is recognizing no cost savings in this proposal for coal-fired utilities as a result of the modification of the housekeeping requirements. In the FEA in support of 2017 Beryllium Final Rule, the Agency listed the housekeeping compliance rate for affected workers at coal-fired utilities at 75 percent and therefore estimated housekeeping costs for the residual 25 percent of utility workers in a beryllium work area. But upon further review, OSHA has preliminarily determined that affected employers in coal-fired utilities were already required to perform comparable housekeeping duties under 29 CFR 1910.1018(k) to prevent accumulations of inorganic arsenic found in coal ash. Accordingly, coal-fired utility compliance rates with the housekeeping requirements for affected workers should have been 100 percent in the prior FEA, and no costs for housekeeping for these workers should have been included in OSHA's cost estimates. Consequently, OSHA is recognizing no cost savings in this proposal for coal-fired utilities as a result of the modification of the housekeeping requirements.

The proposed rule clarification also means that employers in primary aluminum production facilities would typically only be required to comply with the beryllium housekeeping provisions in ''regulated areas,'' which for cost purposes OSHA identified as employees exposed over the PEL in its exposure profile. There are several exceptions, none of which have a quantifiable impact on costs: employers in this industry would still need to follow the housekeeping requirements when cleaning up spills and emergency releases of beryllium (paragraph (j)(1)(ii)), handling and maintaining cleaning equipment (paragraph (j)(2)(v)), and when necessary to reduce some workers exposures below the PEL (serving as an engineering control to prevent over-exposure to beryllium within regulated areas or the need for regulated areas). OSHA did not identify separate costs in its prior FEA for this use of housekeeping as a form of engineering control and does not do so here. Thus, for cost calculation purposes in this new PEA, OSHA removed housekeeping costs for all employees exposed below the PEL in its exposure profile. This proposed change results in an annualized cost savings for employers in primary aluminum production of $323,664 using a 3 percent discount rate and $330,324 using a 7 percent discount rate. Annualized costs by provision and discount rate can be seen below in Tables 2 and 3. OSHA believes that these estimated cost savings might be slightly overstated to the extent that some housekeeping outside of the regulated areas would still be needed to perform an engineering-control function in some facilities, but the Agency is unable to quantify them now because of the variability among facilities and controls that employers may implement to comply with the standard.

e. Additional familiarization. In the FEA in support of OSHA's 2017 Beryllium Final Rule, the Agency determined that employers would need to spend time familiarizing themselves with the rule and allocated 4, 8, and 40 hours, depending on establishment size (fewer than 20 employees, between 20 and 499 employees, and 500 or more employees, respectively). OSHA has similarly preliminarily determined that establishments would need to spend time familiarizing themselves with this proposal. As the affected provisions in this proposal are only a fraction of all the provisions in the 2017 final rule and would not require any new actions on the part of employers, the Agency has estimated familiarization time of 2, 4, and 20 hours per employer, depending on establishment size, for a supervisor to review the changes to the beryllium rule reflected in this proposal. This results in an annualized cost of $9,404 using a 3 percent discount rate and $11,421 using a 7 percent discount rate. Annualized costs by provision and discount rate—3 and 7 percent—can be seen below in Tables 2 and 3, respectively.

f. Unchanged provisions. As discussed earlier, this proposal would primarily serve to clarify OSHA's intent with respect to certain terms and requirements in OSHA's 2017 beryllium general industry standard. These proposed changes largely deal with clarifying the application of various requirements to trace beryllium. The triggers for most provisions in the standard—the PEL, respiratory protection, exposure assessment, regulated areas, medical surveillance, medical removal protection, written exposure control plan, and training provisions[8]—are determined by factors other than beryllium concentration and would be unchanged by this proposal. Similarly, the revised definition of ''emergency'' in this proposal would not affect the costs estimated for the other provisions in the standard.

4. Economic and Technological Feasibility

In the FEA for the 2017 beryllium standard, OSHA concluded that the rule was economically and technologically feasible. This proposal would not impose any new requirements and has the net impact of removing a small amount of cost, so OSHA has preliminarily determined that this proposed rule is also economically and technologically feasible.

5. Effects on Benefits

This proposal would clarify aspects of the 2017 general industry beryllium standard to address unintended

[7] In the previous FEA, OSHA had included costs for head coverings in lieu of showers, reasoning that employees could avoid the need for showers because the head coverings and other PPE would prevent their hair or body parts from becoming contaminated with beryllium.

[8] While the proposed changes in the standard do not mandate any additional employee training, OSHA notes that it had previously accounted for costs of annual re-training required by the standard (Document ID OSHA–H005C–2006–0870–2042, p. V–221).

consequences regarding the applicability of provisions designed to protect workers from dermal contact with beryllium-containing materials and trace amounts of beryllium. This proposal would make clear that OSHA did not, and does not, intend to apply the provisions aimed at protecting workers from the effects of dermal contact to industries that only work with beryllium in trace amounts where there is limited or no airborne exposure. In the prior FEA, OSHA did not identify any quantifiable benefits from avoiding beryllium sensitization from dermal contact (see discussion at p. VII–16 through VII–18). Thus, the revisions in this proposal, which are focused on dermal contact, would not have any impact on OSHA's previous benefit estimates.

6. Regulatory Flexibility Act Certification

This proposal would result in cost savings for affected small entities, and those savings fall below levels that could be said to have a significant positive economic impact on a substantial number of small entities.[9] Therefore, OSHA preliminarily certifies that this proposal would not have a significant impact on a substantial number of small entities.

TABLE 1—TOTAL UNDISCOUNTED NET COST SAVINGS OF THE PROPOSED BERYLLIUM STANDARD BY YEAR
[2017 Dollars]

Application Group	Year									
	1	2	3	4	5	6	7	8	9	10
Aluminum Production	$613,367	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053	$328,053
Coal Fired Utilities	9,461	0	0	0	0	0	0	0	0	0
Total	622,828	328,053	328,053	328,053	328,053	328,053	328,053	328,053	328,053	328,053

[9] OSHA investigated whether the projected cost savings would exceed 1 percent of revenues or 5 percent of profits for small entities and very small entities for every industry. To preliminarily determine if this was the case, OSHA returned to its original regulatory flexibility analysis (in the 2017 FEA) for small entities and very small entities. OSHA found that the cost savings of this proposal are such a small percentage of revenues and profits for every affected industry that OSHA's criteria would not be exceeded for any industry.

TABLE 2—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE PROPOSED BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY

[In 2017 dollars using a 3 percent discount rate]

Application group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	Housekeeping	Training	Total program costs
Aluminum Production													
331313	Alumina Refining and Primary Aluminum Production.	−$240	$0	$0	$2,639	$0	$0	$0	$35,023	$415	$323,664	$0	$361,500
Coal Fired Utilities													
221112	Fossil Fuel Electric Power Generation.	−6,209	0	0	8,087	0	0	0	0	0	0	0	1,878
311221	Wet Corn Milling	−282	0	0	260	0	0	0	0	0	0	0	−22
311313	Beet Sugar Manufacturing	−353	0	0	303	0	0	0	0	0	0	0	−49
311942	Spice and Extract Manufacturing.	−41	0	0	43	0	0	0	0	0	0	0	2
312120	Breweries	−54	0	0	43	0	0	0	0	0	0	0	−11
321219	Reconstituted Wood Product Manufacturing.	−20	0	0	22	0	0	0	0	0	0	0	2
322110	Pulp Mills	−32	0	0	22	0	0	0	0	0	0	0	−10
322121	Paper (except Newsprint) Mills.	−437	0	0	238	0	0	0	0	0	0	0	−199
322122	Newsprint Mills	−705	0	0	519	0	0	0	0	0	0	0	−186
322130	Paperboard Mills	−447	0	0	346	0	0	0	0	0	0	0	−101
325211	Plastics Material and Resin Manufacturing.	−85	0	0	87	0	0	0	0	0	0	0	2
325611	Soap and Other Detergent Manufacturing.	−23	0	0	22	0	0	0	0	0	0	0	−1
327310	Cement Manufacturing	−39	0	0	43	0	0	0	0	0	0	0	4
333111b	Farm Machinery and Equipment Manufacturing.	−24	0	0	22	0	0	0	0	0	0	0	−2
336510b	Railroad Rolling Stock Manufacturing.	−26	0	0	22	0	0	0	0	0	0	0	−4
611310	Colleges, Universities, and Professional Schools.	−387	0	0	195	0	0	0	0	0	0	0	−193
Total:													
	General Industry Subtotal	−9,404	0	0	12,913	0	0	0	35,023	415	323,664	0	362,610
	Construction Subtotal	0	0	0	0	0	0	0	0	0	0	0	0
	Maritime Subtotal	0	0	0	0	0	0	0	0	0	0	0	0
	Total, All Industries	−9,404	0	0	12,913	0	0	0	35,023	415	323,664	0	362,610

TABLE 3—ANNUALIZED NET COST SAVINGS OF PROGRAM REQUIREMENTS FOR INDUSTRIES AFFECTED BY THE PROPOSED BERYLLIUM STANDARD BY SECTOR AND SIX-DIGIT NAICS INDUSTRY

[In 2017 dollars using a 7 percent discount rate]

Application group/NAICS	Industry	Rule familiarization	Exposure assessment	Regulated areas	Beryllium work areas	Medical surveillance	Medical removal provision	Written exposure control plan	Protective work clothing & equipment	Hygiene areas and practices	Housekeeping	Training	Total program costs
Aluminum Production													
331313	Alumina Refining and Primary Aluminum Production.	−$291	$0	$0	$3,205	$0	$0	$0	$35,023	$415	$330,324	$0	$368,675
Coal Fired Utilities													
221112	Fossil Fuel Electric Power Generation.	−7,541	0	0	9,822	0	0	0	0	0	0	0	2,281
311221	Wet Corn Milling	−342	0	0	315	0	0	0	0	0	0	0	−27
311313	Beet Sugar Manufacturing.	−428	0	0	368	0	0	0	0	0	0	0	−60
311942	Spice and Extract Manufacturing.	−50	0	0	53	0	0	0	0	0	0	0	3
312120	Breweries	−66	0	0	53	0	0	0	0	0	0	0	−13
321219	Reconstituted Wood Product Manufacturing.	−24	0	0	26	0	0	0	0	0	0	0	3
322110	Pulp Mills	−39	0	0	26	0	0	0	0	0	0	0	−12
322121	Paper (except Newsprint) Mills.	−531	0	0	289	0	0	0	0	0	0	0	−242
322122	Newsprint Mills	−856	0	0	631	0	0	0	0	0	0	0	−225
322130	Paperboard Mills	−543	0	0	421	0	0	0	0	0	0	0	−123
325211	Plastics Material and Resin Manufacturing.	−103	0	0	105	0	0	0	0	0	0	0	2
325611	Soap and Other Detergent Manufacturing.	−28	0	0	26	0	0	0	0	0	0	0	−2
327310	Cement Manufacturing	−48	0	0	53	0	0	0	0	0	0	0	5
333111b	Farm Machinery and Equipment Manufacturing.	−29	0	0	26	0	0	0	0	0	0	0	−3
336510b	Railroad Rolling Stock Manufacturing.	−31	0	0	26	0	0	0	0	0	0	0	−5
611310	Colleges, Universities, and Professional Schools.	−471	0	0	237	0	0	0	0	0	0	0	−234
Total:													
	General Industry Subtotal	−11,421	0	0	15,682	0	0	0	35,023	415	330,324	0	370,022
	Construction Subtotal	0	0	0	0	0	0	0	0	0	0	0	0
	Maritime Subtotal	0	0	0	0	0	0	0	0	0	0	0	0
	Total, All Industries	−11,421	0	0	15,682	0	0	0	35,023	415	330,324	0	370,022

VII. OMB Review Under the Paperwork Reduction Act of 1995

This proposal contains no information collection requirements subject to OMB approval under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations at 5 CFR part 1320. The PRA defines a *collection of information* as *the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.* See 44 U.S.C. 3502(3)(A). While not affected by this rulemaking, the Department has cleared information collections related to occupational exposure to beryllium standards—general industry, 29 CFR 1910.1024; construction, 29 CFR 1926.1124; and shipyards, 29 CFR 1915.1024—under control number 1218–0267. The existing approved information collections are unchanged by this rulemaking. The Department welcomes comments on this determination.

VIII. Federalism

OSHA reviewed this proposal in accordance with the Executive Order on Federalism (E.O. 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when clear constitutional and statutory authority exists and the problem is national in scope. E.O. 13132 provides for preemption of State law only with the expressed consent of Congress. Any such preemption is to be limited to the extent possible.

Under Section 18 of the OSH Act, 29 U.S.C. 651 *et seq.,* Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as ''State Plan States'' (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State Plan States are free to develop and enforce under State law their own requirements for safety and health standards.

This proposal complies with E.O. 13132. In States without OSHA approved State Plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, this proposal would limit State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA approved State Plans, this rulemaking would not significantly limit State policy options.

IX. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 28 States and U.S. Territories with their own OSHA approved occupational safety and health plans (''State Plan States'') must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.,* because an existing State standard covering this area is ''at least as effective'' as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, must be applicable to both the private and public (State and local government employees) sectors, and must be completed within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States are not required to amend their standards, although the Agency may encourage them to do so. The 28 States and U.S. Territories with OSHA approved occupational safety and health plans are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming; Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands have OSHA approved State Plans that apply to State and local government employees only.

This proposal would clarify requirements and address the unintended consequences associated with provisions intended to address the effects of dermal contact with beryllium as applied to trace beryllium. It would impose no new requirements. Therefore, no new State standards would be required beyond those already required by the promulgation of the January 2017 beryllium standard for general industry. State-Plan States may nonetheless choose to conform to these proposed revisions.

X. Unfunded Mandates Reform Act

OSHA reviewed this proposal according to the Unfunded Mandates Reform Act of 1995 (''UMRA''; 2 U.S.C. 1501 *et seq.*) and Executive Order 12875 (58 FR 58093). As discussed above in Section VI (''Economic Analysis and Regulatory Flexibility Certification'') of this preamble, the Agency preliminarily determined that this proposal would not impose significant additional costs on any private- or public-sector entity. Accordingly, this proposal would not require significant additional expenditures by either public or private employers.

As noted above under Section IX (''State-Plan States''), the Agency's standards do not apply to State and local governments except in States that have elected voluntarily to adopt a State Plan approved by the Agency. Consequently, this proposal does not meet the definition of a ''Federal intergovernmental mandate'' (see Section 421(5) of the UMRA (2 U.S.C. 658(5))). Therefore, for the purposes of the UMRA, the Agency certifies that this proposal would not mandate that State, local, or Tribal governments adopt new, unfunded regulatory obligations. Further, OSHA concludes that the rule would not impose a Federal mandate on the private sector in excess of $100 million (adjusted annually for inflation) in expenditures in any one year.

List of Subjects in 29 CFR Part 1910

Beryllium, General industry, Health, Occupational safety and health.

Signed at Washington, DC, on April 27, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Amendments to Standards

For the reasons stated in the preamble, OSHA proposes to amend 29 CFR part 1910 as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart Z—Toxic and Hazardous Substances

■ 1. The authority section for subpart Z of part 1910 continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657) Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 5101 *et seq.*

■ 2. Amend § 1910.1024 as follows:
■ a. Revise the definition of ''Beryllium work area'' in paragraph (b);
■ b. Add definitions for ''Contaminated with beryllium and beryllium-contaminated'' and ''Dermal contact with beryllium'' in alphabetical order in paragraph (b);
■ c. Revise the definition of ''Emergency'' in paragraph (b);
■ d. Revise paragraph (f)(2);
■ e. Revise paragraph (h)(3)(ii);
■ f. Revise paragraphs (i)(3)(i)(B), (i)(3)(ii)(B), (i)(4)(i) and (ii); and
■ g. Revise paragraphs (j)(1)(i), (j)(2)(i) and (ii), and (j)(3).

The revisions and additions read as follows:

§ 1910.1024 Beryllium.

* * * * *

(b) * * *

Beryllium work area means any work area:

(i) Containing a process or operation that can release beryllium and that involves material that contains at least 0.1 percent beryllium by weight; and

(ii) Where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium.

* * * * *

Contaminated with beryllium and beryllium-contaminated mean contaminated with dust, fumes, mists, or solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight.

Dermal contact with beryllium means skin exposure to:

(i) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight;

(ii) Solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight; or

(iii) Dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight.

* * * * *

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in an uncontrolled and unintended release of airborne beryllium that presents a significant hazard.

* * * * *

(f) * * *

(2) *Engineering and work practice controls.* (i) The employer must use engineering and work practice controls to reduce and maintain employee airborne exposure to beryllium to or below the PEL and STEL, unless the employer can demonstrate that such controls are not feasible. Wherever the employer demonstrates that it is not feasible to reduce airborne exposure to or below the PELs with engineering and work practice controls, the employer must implement and maintain engineering and work practice controls to reduce airborne exposure to the lowest levels feasible and supplement these controls using respiratory protection in accordance with paragraph (g) of this standard.

(ii) For each operation in a beryllium work area that releases airborne beryllium, the employer must ensure that at least one of the following is in place to reduce airborne exposure:

(A) Material and/or process substitution;

(B) Isolation, such as ventilated partial or full enclosures;

(C) Local exhaust ventilation, such as at the points of operation, material handling, and transfer; or

(D) Process control, such as wet methods and automation.

(iii) An employer is exempt from using the controls listed in paragraph (f)(2)(ii) of this standard to the extent that:

(A) The employer can establish that such controls are not feasible; or

(B) The employer can demonstrate that airborne exposure is below the action level, using no fewer than two representative personal breathing zone samples taken at least 7 days apart, for each affected operation.

* * * * *

(h) * * *

(3) * * *

(ii) The employer must ensure that beryllium is not removed from beryllium-contaminated personal protective clothing and equipment by blowing, shaking, or any other means that disperses beryllium into the air.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(B) Employee's hair or body parts other than hands, face, and neck can reasonably be expected to become contaminated with beryllium.

(ii) * * *

(B) The employee's hair or body parts other than hands, face, and neck could reasonably have become contaminated with beryllium.

(4) * * *

(i) Beryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employees enter any eating or drinking area with beryllium-contaminated personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body; and

* * * * *

(j) * * *

(1) * * *

(i) The employer must maintain all surfaces in beryllium work areas and regulated areas as free as practicable of beryllium and in accordance with the written exposure control plan required under paragraph (f)(1) and the cleaning methods required under paragraph (j)(2) of this standard; and

* * * * *

(2) * * *

(i) The employer must ensure that surfaces in beryllium work areas and regulated areas are cleaned by HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure.

(ii) The employer must not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas or regulated areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of airborne exposure are not safe or effective.

* * * * *

(3) *Disposal and recycling.* For materials that contain beryllium in concentrations of 0.1 percent by weight or more or are contaminated with beryllium, the employer must ensure that:

(i) Materials designated for disposal are disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard; and

(ii) Materials designated for recycling are cleaned to be as free as practicable of surface beryllium contamination and labeled in accordance with paragraph (m)(3) of this standard, or place in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this standard.

* * * * *

[FR Doc. 2018–09307 Filed 5–4–18; 8:45 am]

BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0601; FRL–9977–42—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Regional Haze Plan and Visibility for the 2010 Sulfur Dioxide and 2012 Fine Particulate Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; supplemental.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a supplement to its March 1, 2018 proposed approval of the Commonwealth of Virginia's (the Commonwealth or Virginia) request to change reliance on the Clean Air Interstate Rule (CAIR) to reliance on the Cross-State Air Pollution Rule (CSAPR) to address certain regional haze requirements and to convert the Agency's limited approval/limited disapproval of Virginia's regional haze SIP to a full approval. EPA's March 1, 2018 notice of proposed rulemaking (NPR) also proposed to approve the ''visibility element'' of Virginia's infrastructure SIP submittals for the 2010 sulfur dioxide (SO_2) and 2012 fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS). This supplemental proposal clarifies the infrastructure elements the Agency is proposing to approve for the 2010 SO_2 National Ambient Air Quality Standards (NAAQS) and proposes to remove EPA's June 7, 2012 federal implementation plan (FIP) for Virginia which replaced reliance on CAIR with reliance on CSAPR to address certain deficient regional haze requirements identified in the Commonwealth's regional haze state implementation plan (SIP). EPA is seeking comment only on the issues raised in this supplemental proposal and is not reopening for comment other issues raised in its prior proposal. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before June 6, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2017–0601 at *http://www.regulations.gov,* or via email to *spielberger.susan@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, 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. 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, (215) 814–5787, or by email at *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2015, the Virginia Department of Environmental Quality (VA DEQ) submitted a revision to the Virginia SIP to update its regional haze plan to change reliance from CAIR to CSAPR and to meet visibility requirements in section 110(a)(2)(D) of the CAA. On March 1, 2018 (83 FR 8814), EPA published a notice of proposed rulemaking (March 1, 2018 NPR) proposing to take the following actions: (1) Approve Virginia's July 16, 2015 SIP submission that changes reliance on CAIR to reliance on CSAPR for certain elements of Virginia's regional haze program; (2) convert EPA's limited approval/limited disapproval of Virginia's regional haze program to a full approval; and (3) approve the prong 4 portions of Virginia's June 18, 2014 infrastructure SIP submission for the 2010 SO_2 NAAQS and of its July 16, 2015 infrastructure SIP submission for the 2012 $PM_{2.5}$ NAAQS. EPA is not reopening the public comment period to submit comment on the issues addressed in the March 1, 2018 NPR.

II. Specific Issues Addressed in This Supplemental NPR

Removal of Partial Regional Haze FIP

On June 7, 2012, EPA finalized a limited approval and a limited disapproval of several SIP revisions submitted by VA DEQ meant to address regional haze program requirements.[1] The limited disapproval of these SIP revisions was based upon Virginia's reliance on CAIR as an alternative to best available retrofit technology (BART) and as a measure for reasonable progress. To address deficiencies in CAIR-dependent regional haze SIPs for several states, including Virginia, EPA promulgated FIPs that replace reliance on CAIR with reliance on CSAPR to meet BART and reasonable progress requirements in Virginia and other states in that same action. Consequently, for these states, this particular aspect of their regional haze requirements was satisfied by a FIP (hereafter referred to as partial RH FIP). On July 16, 2015, the Commonwealth of Virginia submitted a SIP revision changing its reliance from CAIR to CSAPR in its SIP to meet BART for visibility purposes and for addressing reasonable progress requirements, thereby removing Virginia's need for the partial RH FIP.

In its March 1, 2018 NPR, EPA proposed to approve the July 16, 2015 SIP revision which would change Virginia's reliance upon CAIR to reliance upon CSAPR for the BART and reasonable progress elements of Virginia's regional haze program. EPA also proposed to convert EPA's limited approval/limited disapproval of Virginia's regional haze program to a full approval based on Virginia's SIP revision changing reliance upon CAIR to reliance upon CSAPR. In this action, EPA proposes to remove the Agency's partial RH FIP for Virginia which replaced reliance on CAIR with reliance on CSAPR to address certain deficient regional haze requirements identified in the Commonwealth's regional haze SIP. EPA's proposed action to remove this FIP for Virginia is in accordance with section 110(l) of the CAA and will not impact any regional requirements as Virginia will have, when this action is final, a fully approved regional haze program and the ability to rely on CSAPR for certain regional haze requirements, incorporated in its SIP.

Section 110(a)(2)(J) Visibility Requirement

The CAA requires states to submit, within three years after promulgation of a new or revised NAAQS, SIP revisions meeting the applicable elements of sections 110(a)(1) and (2). SIP revisions that are intended to meet the requirements of section 110(a) of the CAA are often referred to as

[1] 77 FR 33643. Virginia's SIP revisions are dated July 17, 2008, March 6, 2009, January 14, 2010, October 4, 2010, November 19, 2010, and May 6, 2011.

infrastructure SIPs and the elements under 110(a) are referred to as infrastructure requirements. EPA acted on the majority of the infrastructure elements within Virginia's infrastructure SIP submittals for the 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS, but concluded that it would take separate action on 110(a)(2)(J) for visibility for 2010 SO_2 as well as on 110(a)(2)(D)(i)(II) for visibility (also known as prong 4) for both the 2010 SO_2 and 2012 $PM_{2.5}$.[2] [3]

In its March 1, 2018 NPR, EPA proposed to approve prong 4 for both the 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS,[4] however the Agency did not address section 110(a)(2)(J) of the CAA as it relates to visibility protection. For this section, EPA recognizes that states are subject to visibility and regional haze program requirements under part C of the CAA. In the event of the establishment of a new NAAQS, the visibility and regional haze program requirements under part C do not change. Therefore, when EPA took action on Virginia's infrastructure SIP submittal for the 2010 SO_2 NAAQS,[5] the Agency could have approved 110(a)(2)(J) for visibility; however, it inadvertently neglected to do so at that time. EPA is now taking action to remedy this unintentional omission by proposing approval of Virginia's June 18, 2014 infrastructure SIP submittal for the 2010 SO_2 NAAQS specifically for section 110(a)(2)(J) for visibility as well as for prong 4 which we proposed for approval on March 1, 2018.

EPA is soliciting comments on the specific issues discussed in this document referring to the proposed: (1). Removal of the partial regional haze FIP which replaced reliance on CAIR with reliance on CSPAR to address certain regional haze requirements as finalizing our March 1, 2018 NPR will give Virginia's regional haze SIP full approval; and (2). approval of Virginia's June 18, 2014 infrastructure SIP submittal for the 2010 SO_2 NAAQS section 110(a)(2)(J) for visibility (in addition to approval for 110(a)(2)(D)(i)(II)). These comments and those received during the comment period for the March 1, 2018 NPR will be considered before taking final action.

III. Proposed Action

EPA is proposing removal of the partial regional haze FIP which replaced reliance on CAIR with reliance on CSPAR to address certain regional haze requirements and approval of Virginia's June 18, 2014 infrastructure SIP submittal for the 2010 SO_2 NAAQS for section 110(a)(2)(J) for visibility.

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce federally authorized environmental programs in a manner that is no less stringent than their federal counterparts. . . .'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its regional haze program consistent with the federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

- Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and

[2] On March 4, 2015 (80 FR 11557), EPA approved portions of Virginia's June 18, 2014 submittal for the 2010 SO_2 NAAQS addressing the following: CAA section 110(a)(2)(A), (B), (C), (D)(i)(II) for prevention of significant deterioration, (D)(ii), (E), (F), (G), (H), (J) (consultation, public notification, and prevention of significant deterioration), (K), (L), and (M).

[3] On June 16, 2016 (81 FR 39208), EPA approved portions of Virginia's July 16, 2015 submittal for the 2012 $PM_{2.5}$ NAAQS addressing the following: CAA section 110(a)(2)(A), (B), (C), (D)(i)(II) for prevention of significant deterioration, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[4] In its analysis for the March 1, 2018 NPR, EPA proposed to find that if revisions to the Commonwealth's regional haze SIP were fully approved, then the prong 4 portions of Virginia's infrastructure SIP submittal for the 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS meet applicable requirements of the CAA.

[5] *See* 80 FR 11557. (approving Virginia's June 18, 2014 submittal for the 2010 SO_2 NAAQS for CAA section 110(a)(2)(A), (B), (C), (D)(i)(II) for prevention of significant deterioration, (D)(ii), (E), (F), (G), (H), (J) (consultation, public notification, and prevention of significant deterioration), (K), (L), and (M)).

Regulatory Review. This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

• Paperwork Reduction Act (PRA). This action does not impose an information collection burden under the PRA. Therefore, its recordkeeping and reporting provisions do not constitute a ''collection of information'' as defined under 44 U.S.C. 3502(3) and 5 CFR 1320.3(c).

• Regulatory Flexibility Act (RFA). This action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

• Unfunded Mandates Reform Act (UMRA). This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

• Executive Order 13132: Federalism. This action does not have federalism implications. It will 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 the various levels of government.

• Executive Order 13175: Consultation and Coordination with Indian Tribal Governments. This action does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on any 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. Thus, Executive Order 13175 does not apply to this action.

• Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045.

The SIP is not approved to apply on any Indian reservation land as defined in 18 U.S.C. 1151 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).

In addition, pursuant to CAA section 307(d)(1)(B), EPA proposes to determine that this action is subject to the provisions of section 307(d). Section 307(d) establishes procedural requirements specific to certain rulemaking actions under the CAA. Pursuant to CAA section 307(d)(1)(B), the withdrawal of the provisions of the Virginia regional haze regional FIP that apply to changing reliance on CAIR to reliance on CSAPR to address certain deficient regional haze requirements is subject to the requirements of CAA section 307(d), as it constitutes a revision to a FIP under section 110(c) of the CAA. Furthermore, section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to ''such other actions as the Administrator may determine.'' EPA proposes that the provisions of 307(d) apply to EPA's action on the Virginia SIP revision.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: April 19, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2018–09653 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 156, 174 and 180

[EPA–HQ–OPPT–2012–0423; FRL–9977–08]

Withdrawal of Proposed Rules; Discontinuing Several Rulemaking Efforts Listed in the Semiannual Regulatory Agenda

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rules.

SUMMARY: EPA is withdrawing several proposed regulatory requirements described in the proposed rules identified in this document for which the Agency no longer intends to issue a final regulatory action. This document identifies the proposed rules and provides a brief explanation for the Agency's decision not to pursue a final action. The withdrawal of these proposed rules does not preclude the Agency from initiating the same or a similar rulemaking at a future date. It does, however, close out the entry for these rulemakings in EPA's Semiannual Regulatory Agenda. Should the Agency decide at some future date to initiate the same or similar rulemaking, it will add an appropriate new entry to EPA's Semiannual Regulatory Agenda to reflect the initiation of the action, and EPA will issue a new notice of proposed rulemaking.

DATES: As of May 7, 2018, the proposed rules published on November 23, 1994, at 59 FR 60519; November 23, 1994, at 59 FR 60525; June 26, 1996, at 61 FR 33260; and September 17, 1999, at 64 FR 50671, are withdrawn.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPPT–2012–0423, is available at *http://www.regulations.gov* or at the EPA Docket Center (EPA/DC), 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, for the OPP Docket it is (703) 305–5805, and the telephone number for the OPPT Docket is (202) 566–0280. For more information about the docket and instructions about visiting the EPA/DC, go to *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Angela Hofmann, Director, Regulatory Coordination Staff (7101M), Office of Chemical Safety and Pollution Prevention, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–0258; email address: *hofmann.angela@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action is directed to the public in general, and may be of particular interest to those persons who follow proposed rules issued under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since others may also be interested, the Agency has not attempted to describe all the specific entities potentially interested.

II. Why is EPA issuing this withdrawal of proposed rules?

This document serves two purposes:

1. It announces to the public that EPA is withdrawing certain proposed rules

for which the Agency no longer intends to issue a final rule.

2. It officially terminates the ongoing rulemaking activities, which allows the Agency to close out the individual rulemaking entries for these actions that appear in EPA's Semiannual Regulatory Agenda.

All agencies publish Semiannual Regulatory Agendas describing regulatory actions they are developing or have recently completed. These agendas are published in the **Federal Register**, usually during the spring and fall of each year, as part of the Unified Agenda of Federal Regulatory and Deregulatory Actions (Semiannual Regulatory Agenda). The Agency publishes the EPA Semiannual Regulatory Agenda to update the public about: Regulations and major policies currently under development, reviews of existing regulations and major policies, and rules and major policies completed or canceled since the last Semiannual Regulatory Agenda.

The Semiannual Regulatory Agenda is often used as a tool to solicit interest and participation from stakeholders. As such, EPA believes that the public is best served by a Semiannual Regulatory Agenda that reflects active rulemaking efforts. The withdrawal of these inactive rulemaking efforts will streamline EPA's Semiannual Regulatory Agenda and allow the public to better identify and focus on those rulemaking activities that are active.

For the individual reasons described in this document, the Agency has decided not to complete these actions at this time. By withdrawing the proposed rules, the Agency is eliminating the pending nature of that regulatory action. Should the Agency determine to pursue anything in these areas in the future, it will create a new entry in EPA's Semiannual Regulatory Agenda and issue a new proposed rule.

III. Which proposed rules are being withdrawn?

This Unit identifies the proposed regulatory actions that are being withdrawn, provides a summary of what was proposed, and a brief explanation for the Agency's withdrawal. The ''RIN'' refers to the regulatory identification number assigned to the rulemaking effort in the Semiannual Regulatory Agenda.

A. Groundwater and Pesticide Management Plan Rule (PMP); RIN 2070–AC46

1. *What was proposed?* On June 26, 1996 (61 FR 33260; FRL–4981–9), EPA issued a proposed rule to implement a key component of the Agency's 1991 Pesticides and Ground Water Strategy, and it reflected many years of discussions and input from States and other stakeholders. Through the development and use of State Management Plans (SMPs), EPA proposed to restrict the use of certain pesticides by providing States with the flexibility to protect the ground water in the most appropriate way for local conditions. This approach capitalized on the most effective and efficient roles for State and Federal Government to collaborate in the protection of the nation's ground water resources. Using the proposed SMP approach, EPA proposed to restrict the legal sale and use of five pesticides that have been identified as either ''probable'' or ''possible'' human carcinogens—alachlor, atrazine, cyanazine, metolachlor, and simazine. Because of their potential to contaminate ground water, EPA had determined that these pesticides may cause unreasonable adverse effects on the environment in the absence of effective management measures provided by a SMP. The proposed rule announced that the labels of these pesticides would be changed to require use in accordance with an EPA-approved SMP, after a period of time allowed for development and approval of these SMPs. The proposed rule also contained proposed revisions to pesticide labeling regulations, in order to clarify general labeling requirements.

On February 23, 2000 (65 FR 8925; FRL–6491–1), EPA solicited public comments on additional information about metolachlor, which was one of the four pesticides in the proposed rule. In the proposed PMP rule, the Agency proposed, as a condition of continued use, that States and Tribes prepare chemical-specific management plans for four herbicides that have been shown to persist in the environment and leach to ground water, creating a potential unreasonable adverse effect on human health and the environment. Specifically, EPA sought comment on data provided to EPA pertaining to the products containing metolachlor, *S*-metolachlor, and *R*-metolachlor.

2. *Why is it being withdrawn*? Action on the proposal was delayed while the scope of the program described in the proposed rule was reconsidered to determine whether the program could be expanded to address water quality issues in addition to ground water, and to determine the best partnership approach to implementation. More important, the risk level associated with the named pesticides in the proposed rule was also reexamined as part of the FIFRA reregistration process concluded in 2006. As part of that process, EPA determined that all five of the chemicals identified in the SMP proposal met the ''no unreasonable adverse effects on the environment'' standard for FIFRA registration without the steps identified in the proposed rule. These reregistration determinations necessarily mean that the rule is unnecessary to prevent unreasonable adverse effects on the environment, and EPA is therefore withdrawing its proposed rule.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP–36190.

B. Pesticides; Registration Requirements for Antimicrobial Pesticide Products; RIN 2070–AD14

1. *What was proposed?* On September 17, 1999, (64 FR 50671; FRL–5570–6), EPA issued a proposed rule to establish procedures for the registration of antimicrobial products, as well as implement certain new provisions of FIFRA, as amended by the Food Quality Protection Act (FQPA). In addition to registration procedures for antimicrobial products, EPA also proposed to establish labeling standards for antimicrobial public health products, which would ensure that these products are appropriately labeled for the level of antimicrobial activity they demonstrate; to modify its notification process for antimicrobial products to conform to the statutorily prescribed process; and to exempt certain antimicrobial products from FIFRA regulation. EPA proposed new procedures and provisions to streamline and improve the registration process, increase consistency and certainty for antimicrobial producers, reduce the timeframes for EPA decisions on antimicrobial registrations, increase public health protection by ensuring the continued efficacy of antimicrobial public health pesticides, and promote international harmonization efforts. EPA proposed to interpret the applicability of the new FIFRA definition of ''pesticide'' that excludes liquid chemical sterilants from FIFRA regulation and includes nitrogen stabilizers, and to describe requirements pertaining to use dilution labeling. EPA anticipated the proposed rule would provide technical, conforming and organizational changes to portions of its regulations on pesticide registration and labeling for clarity and understanding. On November 16, 1999, (64 FR 62145; FRL–6393–8), EPA extended the comment period for the original proposed rule.

2. *Why is it being withdrawn*? On December 14, 2001 (66 FR 64759; FRL–6752–1) EPA issued a final rule, entitled

''Pesticide Labeling and Other Regulatory Revisions,'' effective February 12, 2002, revising certain labeling regulations for pesticide products for clarity and published an interpretation of the FIFRA as it applies to nitrogen stabilizers. The final rule also revised regulations that contain statutory provisions excluding certain types of products from regulation as pesticides.

The Pesticide Registration Improvement Act (PRIA), which was enacted in 2003, reauthorized October 1, 2007, by the Pesticide Registration Improvement Renewal Act (PRIA 2), and reauthorized again on October 1, 2012 by the Pesticide Registration Improvement Act (PRIA 3), established deadlines and pesticide registration service fees for registration actions. The category of action, the amount of the pesticide registration service fee, and the corresponding decision review periods by year are prescribed in these statutes. These statutory enactments were intended to create a more predictable evaluation process for affected pesticide decisions, and couple the collection of individual fees with specific decision review periods. They also promote shorter decision review periods for reduced-risk applications. EPA now actively provides guidance for PRIA-driven streamlined regulatory determinations for most major pesticide registration actions that is applicable to all pesticide registration types, not just antimicrobial products. (see PRIA guidance *http://www.epa.gov/pesticides/regulating/fees/index.htm*).

The passage and implementation of PRIA and the implementation of the Agency's final rule regarding pesticide labeling and other regulatory revisions of December 14, 2001, have rendered the remainder of what was proposed in the proposed rule moot. For these reasons, EPA is withdrawing the remainder of what was proposed in its proposed rule.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP–36190.

C. Plant-Incorporated Protectants (PIPs); Exemption for Those Derived Through Genetic Engineering From Sexually Compatible Plants; RIN 2070–AD55

1. *What was proposed?* On November 23, 1994 (59 FR 60519; FRL–4755–3) (when proposed, the RIN was 2070–AC02), EPA proposed to exempt from FIFRA regulation those plant-incorporated protectants (then called plant-pesticides) that are not likely to present new exposures to non-target organisms. This exemption was proposed based on the assumption that if a plant normally produces a pesticidal substance, organisms that normally come into contact with the plant have likely been exposed to the substance in the past, perhaps over long periods of time. No new exposures would be likely to occur, and based on long experience with plants in conventional agriculture, such PIPs would meet the FIFRA section 25(b)(2) exemption standard. In defining, for regulatory purposes, those substances for which no new exposures would occur, the Agency proposed to base its approach on the concept of sexual compatibility. Sexually compatible plants are more likely to share common traits than are unrelated plants. If the donor of the genetic material is sexually compatible with the recipient plant, it can be assumed that the genetic material is already present in the sexually compatible plant population and there would be no novel exposures. In the 1994 proposal, the proposed regulatory text did not specify how the genetic material of a plant-incorporated protectant or ''PIP'' could be moved from the donor to the sexually compatible recipient plant, whether through conventional breeding or genetic engineering techniques.

On July 19, 2001 (66 FR 37855; FRL–6760–4), EPA finalized part of its 1994 proposal thereby exempting certain plant-incorporated protectants moved among plants in a sexually compatible population. The 2001 rule defined sexually compatible as meaning a viable zygote is formed only through the union of two gametes through conventional breeding. EPA did not in 2001 finalize that part of the proposal dealing with PIPs moved among plants in a sexually compatible population through genetic engineering but rather requested additional public comment on the issues raised by scientific information discovered between 1994 in 2001, in 1994 in public comment, and by issues raised by the 2000 report of the National Academies of Science (NAS) National Research Council (NRC).

2. *Why is it being withdrawn?* EPA is withdrawing this proposed action because as the Agency's experience with PIPs and greater scientific knowledge have increased, it has become evident to the Agency that were EPA to pursue an exemption for certain PIPs moved among plants in sexually compatible populations through genetic engineering, more appropriate, scientifically current criteria for describing the exempted PIPs should be developed rather than relying on the criteria proposed in 1994.

In 2001, EPA concluded that a high probability exists that PIPs moved between plants in sexually compatible populations through conventional breeding would not present novel exposures to nontarget organisms. Notwithstanding that conclusion, EPA could not (with the same level of confidence) draw the same conclusion for PIPs moved between plants in sexually compatible plant populations through genetic engineering given the limitations of the modification techniques available at that time. In addition, EPA came to agree with the 2000 NRC report that recommended that ''[g]iven that transfer and manipulation of genes between sexually compatible plants could potentially result in adverse effects in some cases . . . EPA should reconsider its *categorical* exemption of *transgenic* [plant-incorporated protectants] derived from sexually compatible plants.'' (NRC 2000 at p. 131, emphasis in original). The NRC report pointed out for example that the Agency's proposed language would exempt genetic material moved among plants in sexually compatible populations through genetic engineering without taking into consideration whether the moved genetic material would be expressed in the same pattern and at the same levels as occurs naturally in the plant (NRC 2000 at p. 129). The proposal is not supported by a sufficient basis to finalize the proposed exemption, especially in light of the scientific developments that have taken place in the last decade.

Recently, newer, more precise techniques of genetic engineering have been developed based on scientific discoveries in genetics and molecular biology since the 1994 proposal and the 2001 rule were issued. These developments will allow the Agency to craft criteria that are scientifically more current and that more accurately describe the PIPs that would be exempted as well as procedures to better ensure that all the PIPs in an exempted category meet the FIFRA section 25(b)(2) exemption standard. Consequently, if EPA were to pursue such an exemption today, the Agency would issue a new proposed rule, based on knowledge of the types of products possible with the newest technology rather than issuing a final rule based on the previous proposals. Withdrawing the 1994 proposal does not preclude the Agency from initiating the same or similar regulatory action in the future. At that time, the Agency will initiate a new regulatory action and create a new entry for the Semiannual Regulatory Agenda. It is also worth noting that the Agency's proposal to exempt certain types of pesticide products from

regulation under FIFRA is entirely a discretionary action; there is no requirement in FIFRA that the Agency promulgate a regulation to exempt products that might satisfy the exemption standard in FIFRA section 25(b)(2). EPA is therefore withdrawing the remainder of this proposal.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP–300369.

D. Plant-Incorporated Protectants (PIPs); Exemption for PIPs That Act by Primarily Affecting the Plant; RIN 2070–AD56

1. *What was proposed?* On November 23, 1994 (59 FR 60519; FRL–4755–3) (when proposed, the RIN was 2070–AC02), EPA proposed, under FIFRA section 25(b)(2), to exempt from most of the requirements of FIFRA those Plant-Incorporated Protectants (PIPs) (in 1994, PIPs were called plant-pesticides (see 59 FR 60525; November 23, 1994)) that act primarily by affecting the plant under the assumption that such PIPs are less likely to be directly toxic to either target pests or to nontarget organisms. The criteria proposed at 40 CFR 174.5(b)(2) describe PIPs that act primarily by affecting the plant as a pesticidal substance so that the target pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of three ways: (a) The pesticidal substance acts as a structural barrier to attachment of the pest to the host plant, a structural barrier to penetration of the pest into the host plant, or a structural barrier to spread of the pest in the host plant, for example, through the production of wax or lignin, or length of trichomes (plant hairs); (b) The pesticidal substance acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest; or (c) The pesticidal substance acts by creating a deficiency of a plant nutrient or chemical component essential for pest growth on/in the host plant.

EPA also indicated in 1994 that it was considering whether to extend this exemption to include substances such as plant hormones, because plant hormones act within the plant to ''primarily affect the plant'' and do not act directly on a target pest.

On July 19, 2001 (66 FR 37855; FRL–6760–4), EPA reopened the comment period on the proposed exemption to allow the public an opportunity to comment on the information, analyses, and conclusions pertaining to PIPs that act primarily by affecting the plant in the report issued in 2000 by the NRC of the NAS entitled ''Genetically Modified Pest-Protected Plants: Science and Regulation'' (National Research Council. 2000. National Academies Press, Washington, DC), and to comment on several risk issues received in public comment on the 1994 proposal (59 FR 60525, November 23, 1994).

2. *Why is it being withdrawn*? Because of new scientific discoveries in the area of genetics and molecular biology the Agency has concluded that neither the original 1994 proposal nor the subsequent 2001 supplemental proposal present a sufficient basis for making the statutory finding required under FIFRA section 25(b)(2) to exempt this class of PIPs. Given the current state of genetic technology, it is possible that the exemption criteria set out in 1994 could exempt PIP products available today that pose different risks than the Agency envisioned when it initially proposed the criteria. In essence, the more limited technological capabilities and understanding of science in 1994 led EPA to propose criteria for a generic exemption that current technologies and scientific understanding have rendered inappropriate. While there may be some PIPs that act primarily by affecting the plant that would meet the FIFRA section 25(b)(2) standard for exemption, the Agency no longer considers its proposed criteria for a generic exemption to fairly restrict available products to only those that ''are of a character which is unnecessary to be subject to'' regulation under FIFRA. 7 U.S.C. 136w(b)(2). EPA is therefore withdrawing this proposal.

The decision to exempt pesticides under section 25(b) of FIFRA is entirely discretionary; there is no requirement that EPA promulgate pesticide exemptions. Withdrawing the proposal does not preclude the Agency from initiating regulatory action in the future for PIPs that act primarily by affecting the plant, *e.g.,* exempting on a case-by-case basis a PIP that acts primarily by affecting the plant when that PIP can be shown to meet the FIFRA section 25(b)(2) exemption standard. At that time, the Agency would initiate a new regulatory action and create a new entry for EPA's Semiannual Regulatory Agenda.

i. *Why the Proposed Exemption Criteria Would Exempt Pesticides that Do Not Meet FIFRA Section 25(b)(2) Safety Standard.* A number of advances in scientific knowledge accumulated since publication of the 1994 proposal to exempt PIPs that act primarily by affecting the plant have contributed to an understanding of how the proposed criteria would exempt from FIFRA requirements PIPs that do not meet the FIFRA 25(b)(2) exemption standard. For example, recent research into plant regulatory mechanisms, *e.g.,* the discovery of, and elucidation of the role of interfering RNAs (RNAi), in gene expression, not available at the time the 1994 proposal was published, contributed to the Agency's determination that the proposed exemption categories were constructed such that there are PIPs in the exempted categories that would not meet the FIFRA section 25(b)(2) standard. RNAi plays a key role in directing development of an organism, as well as controlling the various biological functions necessary to maintaining the life of an organism. RNAi is triggered by dsRNA, and while dsRNA can be native to the cell it can also be introduced from an external source. At the time the exemption was proposed, the role of dsRNA in controlling biological functions in the cell was unknown and the possibility that dsRNA could be introduced into the plant to affect the plant's behavior was not taken into consideration. Had such knowledge been available, the proposed criteria would have been based on substantively different logic.

ii. Consideration of the points made in the 2000 NRC Report. In withdrawing this proposal, EPA has also taken into consideration the points the 2000 NRC report made on the Agency's 1994 proposal to exempt from FIFRA requirements PIPs that act primarily by affecting the plant. The NRC report noted that the Agency's analysis did not consider all of the potential impacts on non-target species of all of the PIPs proposed for exemption, including the possibility that in some instances secondary metabolites affecting non-target organisms could be a by-product of a modification to create a PIP that acts primarily by affecting the plant. The NRC report concluded that based on its considerations a ''[C]ategorical exemption under FIFRA might not be scientifically justifiable'' (NRC 2000 at p. 133). Finally, the NRC report also cautioned the Agency that ''genetic changes that result in production of a specific plant protectant can result in production of biologically active compounds other than the intended plant protectants'' and cautioned that ''EPA should be aware of those unintended changes'' (NRC 2000 at p. 134). Upon further analysis, EPA has concluded that the generic criteria proposed in 1994 to allow exemption of PIPs, did not meet the FIFRA section 25(b)(2) exemption standard.

Given the large number of potential PIPs displaying a wide range of modes of action in the categories circumscribed by each of the proposed exemption

criteria, and advances in knowledge showing scientific concerns with the logic underpinning the criteria as constructed in 1994, the Agency cannot utilize the proposed criteria as a basis for this rulemaking. EPA is therefore withdrawing this proposal.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP–300369. See also related dockets identified by the docket ID numbers OPP–300370 and OPP–300371.

Authority: 7 U.S.C. 136 *et seq.,* 21 U.S.C. 346.

Dated: April 25, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–09206 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0291; FRL–9976–34]

Receipt of a Pesticide Petition Filed for Residues of Diquat in or on Crop Group 6C, Dried Shelled Pea and Bean (Except Soybean); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction.

SUMMARY: EPA issued a notice in the **Federal Register** of September 15, 2017, announcing the 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 6, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2017–0291, 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.*

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. 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 Does this Correction Do?

This notice is being issued to correct PP 7E8571. (EPA–HQ–OPP–2017–0291) in FR Doc. 2017–19692, published in the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL–9965–43) is corrected as follows:

PP 7E8571. (EPA–HQ–OPP–2017–0291). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419, requests to establish a tolerance in 40 CFR 180.226 for residues of the herbicide, diquat (6,7-dihydrodipyrido [1,2-a:2′1′-c] pyrazinediium), and its metabolites in or on Crop Group 6C, dried shelled pea and bean (except soybean) at 0.9 parts per million (ppm). The Method GRM012.03A is used to measure and evaluate the chemical residues of diquat dibromide in commodities. Contact: RD.

Authority: 21 U.S.C. 346a.

Dated: April 26, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2018–09648 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AB18

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking; further delay of effective date.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act, referred to as the ''340B Drug Pricing Program'' or the ''340B Program.'' HHS is soliciting comments on further delaying the

effective date of the January 5, 2017, final rule that sets forth the calculation of the ceiling price and application of civil monetary penalties, and applies to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. HHS proposes to further delay the effective date of the final rule published in the **Federal Register** from July 1, 2018, to July 1, 2019. HHS proposes this action to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking.

DATES: Submit comments on or before May 22, 2018.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB18, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments. This is the preferred method for the submission of comments.
- *Email: 340BCMPNPRM@hrsa.gov.* Include 0906–AB11in the subject line of the message.
- *Mail:* Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

All comments submitted will be available to the public in their entirety. Please do not submit confidential commercial information or personally identifying information that you do not want in the public domain.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

HHS published a notice of proposed rulemaking (NPRM) on June 17, 2015, to implement civil monetary penalties (CMPs) for manufacturers that knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity regarding the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis; and to establish the requirement that a manufacturer charge $.01 (penny pricing) for each unit of a drug when the ceiling price calculation equals zero (80 FR 34583, June 17, 2015). After review of the initial comments, HHS reopened the comment period (81 FR 22960, April 19, 2016) to invite additional comments on the following areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers use when estimating the ceiling price for a new covered outpatient drug; and the definition of the ''knowing and intentional'' standard to be applied when assessing a CMP for manufacturers that overcharge a covered entity.

On January 5, 2017, HHS published a final rule in the **Federal Register** (82 FR 1210, January 5, 2017); comments from both the original comment period established in the NPRM and the reopened comment period announced in the April 19, 2016, notice were considered in the development of the final rule. The provisions of that final rule were to be effective March 6, 2017; however, HHS issued a subsequent final rule (82 FR 12508, March 6, 2017) delaying the effective date to March 21, 2017, in accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, titled ''Regulatory Freeze Pending Review.'' [1]

To provide affected parties sufficient time to make needed changes to facilitate compliance, and because questions were raised, HHS issued an interim final rule (82 FR 14332, March 20, 2017) to delay the effective date of the final rule to May 22, 2017. HHS solicited additional comments on whether that date should be further extended to October 1, 2017. After careful consideration of the comments received, HHS delayed the effective date of the January 5, 2017, final rule to October 1, 2017 (82 FR 22893, May 19, 2017).

HHS later solicited comment on delaying the effective date of the January 5, 2017, final rule to July 1, 2018 (82 FR 39553, August 21, 2017). After consideration of the comments received, HHS delayed the effective date of the January 5, 2017, final rule to July 1, 2018 (82 FR 45511, September 29, 2017).

II. Proposal To Delay the Effective Date of the Final Rule

HHS proposes to further delay the effective date of the January 5, 2017, final rule as HHS intends to engage in additional or alternative rulemaking on these issues, and as discussed in more detail on page 5, the Department believes it would be counterproductive to effectuate the final rule prior to issuance of additional or alternative rulemaking on these issues. HHS is in the process of developing new comprehensive policies to address the rising costs of prescription drugs. Those policies will address drug pricing in government programs, such as Medicare Parts B & D, Medicaid, and the 340B discount drug program. Accordingly, we are proposing to delay the effective date of the final rule entitled ''340B Drug Pricing Ceiling Price and Manufacturer Civil Monetary Penalties Regulation.'' See 82 FR 1210 (Jan. 5, 2017).

This rule is currently scheduled to go into effect on July 1, 2018; we are proposing to delay further the effective date to July 1, 2019. We do not believe that this delay will adversely affect any of the stakeholders in a meaningful way. The final rule implements both penny pricing and a provision in the Affordable Care Act contemplating civil money penalties for those who fail to provide the proper 340B discounts to covered entities. The so-called penny pricing provision would allow manufacturers to charge $0.01 for a drug with when the ceiling price calculation results in a zero amount. As discussed in the January 5, 2017 final rule, a small number of manufacturers have informed HHS over the last several years that they charge more than $0.01 for a drug with a ceiling price below $0.01. However, this is a long-standing HHS policy, and HHS believes the majority of manufacturers currently follow the practice of charging a $0.01. Therefore, the delay of this portion of the regulation would not result in a significant economic impact.

Delaying implementation of the 340B-specific CMPs should have no adverse effect given that other more significant remedies are available to entities that believe that they have not been provided the full discount that they are entitled to receive under the program. This proposed delay, though, will save the healthcare sector compliance costs, as described in the January 5, 2017 issuance of the final rule.

HHS believes that the proposed delay would allow necessary time to consider more fully the substantial questions of fact, law, and policy identified by the Department during its review of the rule pursuant to the aforementioned ''Regulatory Freeze Pending Review,'' memorandum. Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures to comply with a rule that is under further consideration would be disruptive.

[1] See: *https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.*

As background, the January 20, 2017, Executive Order entitled, ''Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal,'' specifically instructs HHS and all other heads of executive offices to utilize all authority and discretion available to delay the implementation of certain provisions or requirements of the Patient Protection and Affordable Care Act.[2] The January 5, 2017, final rule is based on changes made to the 340B Program by the Patient Protection and Affordable Care Act. HHS is proposing to further delay the effective date of the January 5, 2017, final rule to July 1, 2019, to more fully consider the regulatory burdens that may be posed by this final rule.

At this time, HHS seeks public comment regarding the impact of delaying the effective date of the final rule, published January 5, 2017, for an additional 12 months from the current effective date of July 1, 2018, to Ju1y 1, 2019, while a more deliberate rulemaking process is undertaken. HHS is soliciting public comments for a shortened 15-day period because parties have had ample opportunity to comment on the two prior delays of the effective date of the underlying 340B regulation, and the impact of this delay on the regulated community is de minimis. Given the prior opportunities to comment on the underlying proposed regulation and the delays, we do not envision receiving any novel comments. Moreover, we believe that the delay of the CMP authority can be issued without the opportunity for public comment because it delays the effective date of a regulatory restriction. HHS encourages all stakeholders to provide comments on this proposed rule.

III. Regulatory Impact Analysis

HHS has examined the effects 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 8, 2011), the Regulatory Flexibility Act (Pub. L. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. 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 one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB).

HHS does not believe that the proposal to further delay the effective date of the January 5, 2017, final rule will have an economic impact of $100 million or more, and therefore, this NPRM has not been designated as an ''economically significant'' proposed rule under section 3(f)(1) of the Executive Order 12866. The economic impact of having no rule in place related to the policies addressed in the final rule is believed to be minimal.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This action's designation as regulatory or deregulatory will be discussed in the final rule and be informed by comments received in response to this proposed rule.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief for small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

For purposes of the RFA, HHS considers all health care providers to be small entities either by meeting the Small Business Administration (SBA) size standard for a small business, or by being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $7 million to $35.5 million. As of January 1, 2018, over 12,800 covered entities participate in the 340B Program, representing safety-net health care providers across the country. HHS has determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small manufacturers; therefore, we are not preparing an analysis of impact for this RFA. HHS estimates that the economic impact on small entities and small manufacturers would be minimal. HHS welcomes comments concerning the impact of this proposed rule on small manufacturers.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' In 2017, the threshold level was approximately $148 million. HHS does not expect this rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This proposed rule would not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and

[2] See: *https://www.gpo.gov/fdsys/pkg/FR-2017-01-24/pdf/2017-01799.pdf.*

responsibilities among the various levels of government.''

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This proposed rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. This proposed rule would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

Dated: May 1, 2018.

George Sigounas,

Administrator, Health Resources and Services Administration.

Approved: May 2, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–09711 Filed 5–4–18; 8:45 am]

BILLING CODE 4165–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 2, 90

[WP Docket No. 07–100; FCC 18–33]

4.9 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In 2002, the Commission allocated the 4940–4990 MHz (4.9 GHz) band for fixed and mobile use and designated the band for public safety broadband communications. Since then, the band has experienced relatively light usage compared to the heavy use of other public safety bands. In this document, the Commission proposes several rule changes and seeks comment on alternatives with the goal of promoting increased public safety use of the band while opening up the spectrum to additional uses that will encourage a more robust market for equipment and greater innovation. The Commission proposes rules on channel aggregation, aeronautical mobile use, frequency coordination, site-based licensing, regional planning, and technical rule changes with the goal of promoting increased use of the band. The Commission seeks comment on alternatives such as expanding eligibility, spectrum leasing, sharing, and redesignating the band for commercial use.

DATES: Submit comments on or before July 6, 2018. Submit reply comments August 6, 2018.

ADDRESSES: You may submit comments, identified by WP Docket No. 07–100 by any of the following methods:

- *Federal Communications Commission's website: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- *Hand or Messenger Delivery:* 445 12th St., SW, Room TW–A325, Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Thomas Eng, Policy and Licensing Division, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW, Washington, DC 20554, at (202) 418–0019, TTY (202) 418–7233, or via email at *Thomas.Eng@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Sixth Further Notice of Proposed Rulemaking (*Sixth FNPRM*) in WP Docket No. 07–100, adopted on March 22, 2018 and released as FCC 18–33 on March 23, 2018. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. Alternative formats (computer diskette, large print, audio cassette, and Braille) are available to persons with disabilities or by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at (202) 418–0530, TTY (202) 418–0432. This document is also available on the Commission's website at *http://www.fcc.gov.*

Comments

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See *Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

Introduction

The Commission has allocated and designated 50 megahertz of spectrum in the 4.9 GHz band (4940–4990 MHz) to public safety. Although nearly 90,000 public safety entities are eligible under our rules to obtain licenses in the band, there were only 2,442 licenses in use in 2012 and only 3,174 licenses in use nearly six years later in 2018. With no more than 3.5% of potential licensees using the band, we remain concerned that, as the Commission stated in 2012, the band has ''fallen short of its potential.''

Public safety entities have offered several reasons why the band has seen less use than expected. One reason cited is the difficulty of acquiring equipment and the cost of deployment. According

to the Association of Public-Safety Communications Officials International's (APCO) 4.9 GHz Task Force Report (APCO Report), ''the public safety user community remains small relative to the greater consumer marketplace,'' which ''has historically resulted in a limited vendor ecosystem, specialized devices, and higher costs.'' We also believe that a lack of available equipment for mobile applications has impeded widespread use of the band by public safety. The National Public Safety Telecommunications Council (NPSTC) has argued that interference concerns have also suppressed use of the 4.9 GHz band. In its 4.9 GHz NPSTC Plan Recommendations Final Report (NPSTC Plan), NPSTC notes that because the Commission's current rules ''allow geographically based licensing with little documentation on system design and transmitter location,'' public safety ''contemplating new service in this band cannot determine if other agencies in their area might cause harmful interference today or in the future.''

In this *Sixth FNPRM,* we seek comment on several alternatives to stimulate expanded use of and investment in the 4.9 GHz band, drawing on comments in the record as well as the NPSTC Plan submitted in 2013 and the APCO Report submitted in 2015. Our goal is to ensure that public safety continues to have priority in the band while opening up the band to additional uses that will facilitate increased usage, including more prominent mobile use, and encourage a more robust market for equipment and greater innovation, while protecting primary users from harmful interference. We believe that with an appropriate sharing mechanism in place, which we discuss in further detail below, our proposed approach will promote more opportunistic use of the 4.9 GHz band without compromising the integrity and security of public safety operations.

Background

In June 2012, the Commission released the Fifth Further Notice of Proposed Rulemaking (*Fifth FNPRM)* in which it sought comment on rule changes intended to establish frequency coordination procedures for 4.9 GHz operations and to encourage spectrum efficiency and greater use of the 4.9 GHz band. It sought comment on how 4.9 GHz licensees currently use this spectrum, what applications and uses are best suited for the band, and what are the most cost-effective ways to improve accessibility to the band while minimizing adverse impact on incumbent operations. The Commission sought views on alternative frequency coordination proposals for 4.9 GHz licensees. The Commission also sought comment on specific proposals regarding expanded eligibility for critical infrastructure industry (CII) entities, for commercial entities on a secondary basis, subject to a shutdown feature, and for the First Responder Network Authority (FirstNet). The Commission also sought comment about the impact of the Middle Class Tax Relief and Job Creation Act of 2012 (Spectrum Act) on broadband uses of the 4.9 GHz band by public safety entities. Finally, the Commission sought comment on whether to allow aeronautical mobile use in the 4.9 GHz band.

The responsive comments to the *Fifth FNPRM* illustrate the wide variety of existing systems operating in the 4.9 GHz band and underscore the importance of developing rules that promote flexible use and maximize spectrum efficiency. Since the *Fifth FNPRM* the Commission has continued to build the record on the 4.9 GHz band. In October 2013, NPSTC submitted detailed recommendations in the NPSTC Plan, and the Public Safety and Homeland Security Bureau (Bureau) released a Public Notice seeking comment on the proposals in the NPSTC Plan. In September 2015, the APCO Report provided additional recommendations on how to increase public safety use of the band, reduce equipment costs, and drive investment in up-to-date technology in the band.

Sixth Further Notice of Proposed Rulemaking

Taking into consideration the record in response to the *Fifth FNPRM,* comments on the NPSTC Plan, the APCO Report, and more recent *ex parte* filings, we now propose a limited set of rules for the 4.9 GHz band to promote more flexible and intensive use of this spectrum while preventing interference. We also seek comment on current usage and what types of services are being provided. Our goals are (a) to support the needs of public safety while opening the band to other compatible uses, (b) to maximize spectral efficiency and usage, (c) to promote a common equipment ecosystem that will drive down equipment costs and stimulate investment through economies of scale, (d) to encourage innovation, and (e) to ensure that secondary users do not cause interference to primary users.

In this *Sixth FNPRM,* we review the major issues previously identified in the *Fifth FNPRM;* in the NPSTC Plan and the APCO Report and in comments on both of these evaluations; and in subsequent ex parte proposals. We then propose and seek comment on specific rules and policies intended to address each issue, and seek comment on and solicit alternative proposals.

Band Plan

In the *Fifth FNPRM,* the Commission sought comment on the current 4.9 GHz band plan, which divides the band into ten one-megahertz channels (Channels 1–5 and 14–18) and eight five-megahertz channels (Channels 6–13), and limits channel aggregation bandwidth to 20 megahertz. The NPSTC Plan proposes to keep this channelization, but recommends aggregating Channels 1–5 into a single 5 megahertz channel designated for air-to-ground communications and robotic use and proposes to reduce the current channel aggregation limit from 20 to 10 megahertz. The APCO Report proposes no band plan changes but calls for relaxing the 20 megahertz channel aggregation limit, arguing that this would enable the band to accommodate 40 megahertz products that are currently available only outside the U.S., which relaxation could ''create a better business case for manufacturers,'' and would ''provide more options for rural deployments.''

Discussion. Most commenters express support for the NPSTC band plan proposal. Based in part on the NPSTC band plan, we propose to retain the existing channelization plan for the band, but we seek comment below on more flexible aggregation limits, and in the Aeronautical Mobile and Robotic Use section, we propose to modify the 4.9 GHz band plan by aggregating Channels 1–5 to form a five-megahertz bandwidth channel for aeronautical mobile and robotic use. Although current geographic licenses authorize use of the entire 50 megahertz by all qualified services, we envision that under our revised rules we would grant licenses for specific uses that would authorize specific channels. We are concerned that the current geographic licensing model does not provide sufficient information on specific channel usage to facilitate effective frequency coordination, which we propose below for the 4.9 GHz band. For example, we seek comment on licensing base stations and hot spots site-by-site rather than blanket geographic licensing, and licensing these stations and mobiles for a specific channel or channels instead of the entire band, to the extent that channel use is static. Does 4.9 GHz equipment dynamically change channels as needed throughout

the band to avoid interference? We seek comment on these proposals.

We further propose to expand the existing channel aggregation bandwidth limit to 40 megahertz and seek comment on that proposal, which could provide more options of the type advocated in the APCO Report, such as new rural deployments, and may enable public-safety access to 5G technologies. We seek comment on this proposal. We are concerned that narrowing the limit to 10 megahertz as proposed in the NPSTC Plan would constrain flexibility and discourage use of innovative broadband technologies. We nonetheless propose to allow Regional Planning Committees (RPCs) to submit plans to limit aggregations to 20 megahertz. We solicit alternative band plan suggestions or modifications to the above. For example, should we permanently aggregate Channels 6–9 and 10–13 to form two 20-megahertz channels? We seek comment about the relative costs and benefits of wider channels. Are wider channels needed to drive innovation of equipment in the band, or are the current aggregation limits sufficient?

We agree with commenters that any reconfiguration or repurposing of the 4.9 GHz band should not force incumbent licensees to modify, abandon, or replace existing 4.9 GHz facilities, which would impose technical, operational, and financial burdens on those incumbents. Therefore, we propose to grandfather all incumbent users as of the date any final rules become effective. As we discuss below in the Database and Existing Licensees section, we further propose that those incumbent licensees whose authorizations currently encompass the entire 4.9 GHz band must certify the channels they actually use when they input their transmitter and receiver parameters into the Commission's Universal Licensing System (ULS) database. Only those channels for which operating parameters have been supplied would receive protection. We seek comment on this approach, under which all new primary and secondary users of the band will be required to coordinate around and protect incumbent users. We also seek comment on whether a temporary licensing freeze before the release date of a report and order in this proceeding and lasting until the effective date of the final rules would be necessary to prevent the filing of applications for systems that are incompatible with the modified band plan.

Aeronautical Mobile and Robotic Use

In the *Fifth FNPRM,* the Commission sought comment on whether to lift the general prohibition on aeronautical mobile operations in the 4.9 GHz band. The Commission proposed to revise § 90.1205(c) to permit aeronautical mobile operation in the band on a secondary, non-interference basis to 4.9 GHz terrestrial services and subject to demonstrating interference protection to radio astronomy (RAS) operations. The Commission sought comment on whether to impose restrictions or conditions on aeronautical mobile use, such as an altitude limit of 1500 feet above ground.

Eight parties filed comments to the *Fifth FNPRM* in support of allowing aeronautical mobile operations under such conditions. The National Academy of Sciences Committee on Radio Frequencies (CORF), an organization representing RAS observatories, requests the following conditions: (1) Make the aeronautical use secondary to terrestrial services, including RAS; (2) limit the altitude of use of this band to 1500 feet above the altitude of the observatory and limit operation to greater than 50 miles from observatories; (3) require aeronautical mobile applicants within 50 miles of protected observatories to demonstrate that the former will protect the latter from interference; and (4) require applicants within 50 miles of protected observatories to certify that they have served a copy of their application on such observatories. AASHTO recommends that air-to-ground operations that employ omnidirectional antennas should be limited to low power, while operations using steerable directional antennas that minimize interference to terrestrial users could employ higher power. FCCA/IAFC/IMSA recommend a maximum altitude of ''500 feet above ground for direct, non-directional air-to-ground video feeds,'' a maximum bandwidth of five megahertz for a video feed, and a requirement that ''aircraft providing video feeds to fixed remote receive sites must use steerable antennas and be limited to 1500 feet above ground level.''

The NPSTC Plan recommends aggregating Channels 1–5 into a five-megahertz channel to be used for air-to-ground communications and robotic communications. The NPSTC Plan would permit transmissions at altitudes up to 400 feet above ground level, and at higher altitudes if the licensee has a waiver. The proposal would require aeronautical mobile operations with an area of operation less than 80.5 km from listed RAS sites to obtain concurrence from the affected RAS site. NPSTC proposes licensing robotic operations on Channels 1–5 on a shared basis with air-to-ground operations, not allowing Channels 1–5 to be used for point-to-point (P–P) communications, and migrating existing users to other channels. APCO also supports these proposals, noting that ''modification of the existing rules, using the guidelines proposed in the NPSTC recommendations, would allow use of the 4.9 GHz band for air to ground communications, would add to the available public safety portfolio, and would assist with increasing public safety use of the spectrum.'' APCO also supports ''following the proposal contained in the NPSTC report with regard to robotic operations to allow for use of 4.9 GHz spectrum on a controlled and limited basis for robotic applications.''

Discussion. We propose to designate Channels 1–5 as aeronautical mobile channels in the 4.9 GHz band. The proposed channel selection provides spectral separation from RAS operations in the 4950–4990 MHz band. As NPSTC notes, the 4.9 GHz band is an ideal short range band with the bandwidth required to transmit video from air to ground. Moreover, many law enforcement agencies operate helicopters and planes using video cameras and so could benefit from this rule change.

We also propose to designate Channels 1–5 for robotic use. Although law enforcement has been using robots for several years, these devices currently operate on an unlicensed basis and are unprotected from interference. Modifying our rules to allow robotic operations could thus improve public safety. We seek comment on the relative costs and benefits of adding robotic use to this band. Is interference likely to be a problem for public safety robots? We propose to limit aerial transmitted information to video payload and to prohibit use of the 4.9 GHz band for aircraft (including unmanned aircraft systems) command and control. We seek comment on these proposals and also request commenting parties to address whether similar restrictions on payload and command and control frequencies should be imposed on robotic uses.

One of the potential cost of these rules would be that, for other than grandfathered licensees, the public safety use of Channels 1–5 would be limited to aeronautical mobile and robotic operations. We seek comment on the extent to which limiting the flexibility of spectrum use in this manner imposes costs by, *e.g.,* creating cumbersome regulatory obstacles to repurposing the spectrum for alternative public safety needs that may become more pressing as circumstances change. Are there any countervailing benefits in

establishing these proposed use restrictions? We also seek comment on the potential benefits of the proposed rule apart from such restrictions. Such benefits, which may be significant, would include that aeronautical mobile functionality would provide to first responders, who could use Channels 1–5 to transmit airborne video of emergency scenes such as wildfires, vehicle pursuits, and other events to assist in response and recovery efforts. A benefit of using these channels for robotic operations would be to enhance first responder safety by allowing users to send remote controlled, camera-equipped mobile devices into potentially dangerous situations. We seek comment on the magnitude of these and any other relative costs and benefits.

Because we decline to propose mandatory relocation of incumbent terrestrial users on Channels 1–5, we therefore propose to require aeronautical mobile and robotic operations to be frequency coordinated around incumbent terrestrial users of Channels 1–5, consistent with the frequency coordination procedures proposed in the Coordination section below, including RPC review. We seek comment on the relative costs and benefits of this coordination requirement. Once aeronautical mobile and robotic operations are licensed, we propose to grant them co-primary status on Channels 1–5. Therefore, during an incident or emergency requiring such use, they would be able to operate on an equal basis with terrestrial users, around which they have already been coordinated, presenting a minimal risk of interference. To prevent future terrestrial licensing in the 4940–4945 MHz segment, we propose to revise § 90.1207 so terrestrial-based licenses are only available in the 4945–4990 MHz segment rather than the entire band. We seek comment on the relative costs and benefits of these proposals and alternative approaches.

While we propose to allow manned aeronautical use of Channels 1–5, we believe it would be premature at this time to permit unmanned aerial systems (UAS) to transmit in the 4.9 GHz band. The Federal Aviation Administration's (FAA) part 107 rules limit small UAS operations to 400 feet altitude above ground, require visual line of sight aircraft operation, prohibit operations over people, and prohibit operation in certain airspace, among other restrictions. The FAA's UAS altitude limit is well below our proposal of 1500 feet above ground, and the other restrictions may present impediments to effective public safety use of UAS. Moreover, the Commission has not yet issued service rules for UAS operations in any specific spectrum band. Nevertheless, we seek comment on the potential for the 4.9 GHz band to support possible future UAS payload operations.

We propose to establish a maximum altitude limit of 1500 feet (457 meters) above ground level (AGL) for manned airborne operations on Channels 1–5. We believe this limit allows greater flexibility than NPSTC's proposal of 400 feet and is consistent with the altitude limit adopted for air-to-ground communications in the 700 MHz narrowband spectrum. However, because FAA rules require fixed-wing aircraft to maintain certain clearances around structures, we propose to allow fixed-wing aircraft to transmit at altitudes exceeding 1500 feet AGL, but only to avoid obstructions, and then only in the immediate area of the obstruction. We seek comment on the terrestrial interference potential and coverage of fixed-wing aircraft compared to the interference potential and coverage of helicopters, and whether any restrictions or prohibitions should apply to either group of aircraft.

We propose to allow air-to-ground and robotic transmissions only from low power devices as defined in § 90.1215 of our rules, which limits maximum conducted output power to 14 dBm per 5 megahertz bandwidth and use of a directional antenna to confine radiation to the direction of the associated receiving antenna. We seek comment on this proposed power limit, as well as on other techniques to minimize interference. For example, AASHTO and LA County propose to allow use of higher powered steerable directional antennas for air-to-ground communications, while Vislink contends that some air-ground communications will require omnidirectional antennas. We seek comment on the current state of aerial steerable directional antenna technology and the associated cost of such equipment.

To minimize the impact of 4.9 GHz aeronautical and robotic operations on the important work being done by RAS observatories, we propose that aeronautical mobile and robotic operations, as with all other 4.9 GHz band operations, make every effort to protect the RAS observatories listed in our rules. We propose that aeronautical mobile use shall generally be prohibited within 80.5 kilometers from a listed RAS site. Public safety entities seeking authorization for aeronautical mobile operations fewer than 80.5 kilometers from a listed RAS site would be required to submit a waiver request and notify and obtain concurrence from the affected observatory. Next, we propose to apply the L emission mask to aeronautical mobile devices on Channels 1–5, which will provide attenuation of 40 dB at 4950 MHz and above to minimize emissions into RAS. We do not propose to require robotic operations to maintain 80.5 km spacing to RAS sites. Robotic operations are transient and, because of their lower antenna elevations relative to airborne operations, do not pose an equivalent interference issue. Moreover, RAS sites are typically located in remote areas where robotic operations are unlikely to take place. We seek comment on our conclusion concerning the interference potential of robotic operations to RAS operations and on any burdens that these proposed RAS protection rules would impose, including the burden placed on small entities.

Next, we propose to amend § 2.106 of the Commission's rules to remove the prohibition on aeronautical mobile service use from the 4940–4950 MHz band in the non-Federal Table of Frequency Allocations, *i.e.,* we propose to reallocate the lower 10 megahertz segment of the 4940–4990 MHz band from the ''mobile except aeronautical mobile'' service to the ''mobile'' service. This action would parallel the International Table and provide the Commission with additional flexibility with regard to the future use of the mobile service. We request comment on this proposal.

Finally, we remind commenters that the United States has border agreements with Canada and Mexico for the 4.9 GHz band that limit potential air-ground operations in border areas. In the Canada Agreement, the Commission agrees not to authorize aeronautical mobile stations within 160 kilometers of the border area without the written consent of Innovation, Science and Economic Development Canada (ISED). In the Mexico Agreement, for stations operated in aircraft, power flux density shall not exceed −114 dBW/m2 in any 1 MHz bandwidth at or beyond the common border. Thus, any rules we may adopt authorizing aeronautical use will be subject to these restrictions in border areas. However, we retain the option of seeking future revision of these cross-border agreements through appropriate international channels. The limits arising from these international agreements would continue to apply to all licensees in the 4.9 GHz band, including aeronautical and robotic uses.

Coordination

Our rules currently require 4.9 GHz licensees to ''cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities,'' but do not require prior frequency coordination. We note that current 4.9 GHz band licenses authorize use of the entire band and are geographic rather than site-based. Thus, they allow licensees to deploy base stations, mobile units, and temporary fixed stations anywhere within the licensee's jurisdiction using any part of the spectrum band by informally coordinating with other uses, and without having to obtain prior clearance from the Commission. In the 2009 FNPRM in this proceeding, the Commission expressed concern that informal self-coordination ''may not ensure that applicants for primary permanent fixed stations offer sufficient protection to other primary permanent fixed stations and other co-primary users.'' Accordingly, the Commission proposed a notice-and-response coordination procedure conducted among applicants and licensees similar to the procedure used for point-to-point (P–P) microwave applications under part 101 of the Commission's rules. However, in the *Fifth FNPRM,* the Commission acknowledged the views of the majority of commenters that notice-and-response coordination ''may not be appropriate for this band because [it] would add a level of uncertainty and complexity to the coordination process,'' and sought comment on requiring 4.9 GHz applications to be submitted to a third party such as a certified public safety frequency coordinator or an RPC. Most commenters to the *Fifth FNPRM* supported certified frequency coordination for the 4.9 GHz band, although a few commenters argued that the status quo of self-coordination is working.

NPSTC's Plan proposes that 4.9 GHz applications be coordinated by a certified public safety frequency coordinator. APCO supports NPSTC's recommendation because ''many public safety users and manufacturers choose not to invest in the 4.9 GHz band because it is not coordinated.'' Specifically, APCO reports that ''the current jurisdictional licensing model is viewed within the public safety community as too similar to an unlicensed structure to provide the degree of confidence needed for mission critical communications, including sensitive transmissions.'' APCO asserts that ''new frequency coordination procedures designed to improve usage, performance, and interference protection would encourage public safety entities that have been reluctant in the past to begin utilizing the 4.9 GHz Band.''

Discussion. We propose to require certified frequency coordination for licensing in the 4.9 GHz band. Given that our goal is to encourage a wide variety of uses of the 4.9 GHz band, we agree with NPSTC, APCO, and the majority of commenters that neither self-coordination nor a notice-and-response coordination procedure is likely to be sufficient to ensure interference protection to primary users in a mixed use environment. We seek comment on this view. We do not propose to require incumbent 4.9 GHz licensees to submit to frequency coordination for their existing operations. Rather, as noted above, we propose to grandfather incumbent operations provided that they file certain technical information on P–P, point-to-multipoint (P–MP), base, and mobile operations in our licensing database as discussed infra in the Database and Existing Licensees section.

We propose that, subject to qualification criteria, Public Safety Pool frequency coordinators which the Commission has certified to coordinate in other part 90 spectrum bands should be eligible to coordinate applications in the 4.9 GHz band. We seek comment on whether to limit 4.9 GHz band coordination to public safety coordinators or whether to allow coordination by non-public safety coordinators as well. To ensure that coordinators are qualified to address band-specific coordination issues, we propose to require all frequency coordinators seeking to coordinate in the 4.9 GHz band to submit a qualification showing, which would include a coordination plan and a showing of expertise specifically for the 4.9 GHz band. We further propose to direct the Public Safety and Homeland Security Bureau to certify coordinators for the band. We seek comment on these proposals, including whether a qualification showing would place a burden on small entities. Current public safety frequency coordinator fees for frequency pair/site combinations range from $60 to $315 depending on the frequency band. We seek comment on the relative costs and benefits of frequency coordination.

The NPSTC Plan proposed that frequency coordinators would send each application to the applicant's home RPC for a five-business day review. We believe this particular proposal is burdensome on RPCs and redundant with the frequency coordinator's function and invite comment on this tentative conclusion. However, NPSTC also proposed that any application where the power flux density (PFD) into an adjacent region border exceeds −109 dBW/m2 would be flagged to be sent to the adjacent RPC to review. We believe this proposal may help prevent interference between regions, so we propose to adopt it. We seek comment on whether this PFD is an appropriate threshold, how PFD should be calculated and predicted, and how a PFD dispute would be resolved. We seek comment on what reference bandwidth should apply to this proposed PFD limit, *e.g.,* is a 5 megahertz bandwidth appropriate?

Finally, we seek comment on whether waiving frequency coordination for certain technology could serve as incentive for manufacturers and licensees to use such technology in the 4.9 GHz band without creating harmful interference. Should we exempt certain short term uses from frequency coordination, such as public safety robotic uses or ad hoc mobile networks? If so, how could such users minimize interference potential to existing operations in the same areas?

Database and Existing Licensees

In the *Fifth FNPRM,* the Commission noted that ULS does not contain information specifying receiver location for 4.9 GHz band P–P or P–MP links, geographically licensed base station coordinates, antenna gain, output power, and antenna height. Because a frequency coordinator lacking this information would have difficulty protecting incumbent primary fixed links and base stations from interference from new operations, the *Fifth FNPRM* proposed to require all current 4.9 GHz licensees to register the technical parameters of their permanent fixed P–P, P–MP, and base-to-mobile stations, including permanent fixed receivers when applicable, into a coordination database to ensure that primary operations receive proper interference protection. The Commission ''tentatively concluded that the most cost-effective option is for the Commission to create and maintain a 4.9 GHz registration database that is modeled after an existing database,'' such as the millimeter wave band registration database in ULS. The Commission also sought comment on whether to use a third party database such as the Computer-Assisted Pre-Coordination Resource and Database (CAPRAD) or a dynamic database similar to the Television White Space (WS) database.

Commenters generally agree that the 4.9 GHz band is hampered by lack of a reliable database that provides technical information about current licensee deployments. The APCO Report concludes that wider use of the 4.9 GHz band is inhibited by ''blanket geographical licensing for fixed and mobile operations on any channel across the band,'' and therefore proposes that ''all fixed locations be identified and licensed for a specific channel or channels.'' The NPSTC Plan proposes that incumbent licensees be required to ''relicense using the proposed frequency coordination process and appropriate ULS schedules'' within one year from when ULS is ready to accept applications using the new process. It also proposes that incumbent licensees that do not conform to the new band plan (including any region-specific variations) must modify their licenses within five years of the adoption of new rules.

The NPSTC Plan recommends using ULS to compile the information needed for coordination because ''ULS is already funded'' and ''data required for coordination is already collected by ULS in the application process.'' NPSTC opposes using a private database that would ''require the applicants to fund the entire cost of capturing, storing, and making data available to coordinators.'' However, other commenters suggest establishing a geo-location database similar to the WS database, so that commercial and unlicensed users could use the 4.9 GHz band on a secondary basis.

Discussion. Our rules specify that 4.9 GHz licensees encountering or causing harmful interference are expected to cooperate and resolve the problem by mutually satisfactory arrangements. Based on the record in this proceeding, we believe that concerns from public safety users of this band regarding resolution of interference issues in the 4.9 GHz band would be addressed if more complete technical information is available to all affected parties. Therefore, we propose to require incumbent licensees and new applicants to provide technical information that will enhance frequency coordination and help mitigate the possibility of interference, while permitting more new users, thereby promoting more efficient use of spectrum that has long been underutilized. We solicit alternative suggestions that would achieve these goals.

We believe ULS provides the most efficient and cost-effective means to facilitate certified frequency coordination in the 4.9 GHz band because it is both flexible and easily accessible to frequency coordinators, incumbent licensees, applicants, and other interested parties. While the Commission relies on private databases in other select spectrum bands, ULS is already set up for licensing in the 4.9 GHz band, and the Commission can use existing form schedules to capture P–P, P–MP, fixed receiver, base station, and mobile station data. Accordingly, we propose to add the 4.9 GHz band to the microwave schedule for P–P, P–MP, and fixed receiver stations. We also propose to uncouple base and mobile stations from geographic licenses and instead require that base and mobile technical parameters be entered on the existing location and technical data schedules. Thus, we propose to maintain ULS as the comprehensive licensing database for the 4.9 GHz band, which frequency coordinators will use to base their coordination. This proposal would not affect or restrict frequency coordinators' use of their own internal databases, which draw licensing data from ULS on a regular basis. We propose to modify ULS as necessary to accept the necessary licensing data, prepare application instructions, and release a public notice to announce when ULS is ready to accept such applications. Regarding the burdens associated with the Commission's application for radio service authorization, the Commission has estimated that ''each response to this collection of information will take on average 1.25 hours.'' The estimate ''includes the time to read the instructions, look through existing records, gather and maintain required data, and actually complete and review the form or response.'' We seek comment on whether these time and cost burdens are accurate, and on the number of entities (incumbents and new entrants) likely to be subject to this requirement. We also seek comment on how best to measure the benefits emanating from this filing requirement in order to determine whether its benefits exceed its relative costs. For example, what is the cost of resolving current and potential interference problems in the absence of such a filing requirement? We seek comment on this proposal, and on the feasibility of alternative database solutions.

We propose to set a one-year timetable, starting on the release date of the ULS public notice described above, for incumbent licensees to provide data, as recommended in the NPSTC Plan. We propose one year because we believe this gives licensees sufficient time to gather technical information about their site-based facilities and file applications, while providing a reasonable date certain that ULS will be sufficiently populated with site-based data to enable accurate frequency coordination. We propose to establish an application process for existing licensees with geographic licenses to identify P–P, P–MP, fixed receivers, base stations, and mobiles that are not licensed site-by-site. Under this process, incumbent licensees would file one or more applications, and update or delete the existing licenses as necessary to eliminate redundancy following a Public Notice announcing that ULS is ready to accept such applications. There would be no fee for the application process since only public safety eligible entities are currently authorized in the band, and the Commission does not charge application fees for public safety entities. We seek comment on this proposal.

AASHTO suggests that incumbent licensees should be required to submit to frequency coordination either when their licenses are set for renewal or within one calendar year of the Commission's adoption of coordination requirements. We disagree because the purpose of the application process is to collect missing incumbent data so that fixed operations would be visible in the database. Although a richer database will better aid future coordinations, coordination of incumbents is not necessary to accomplish this goal and would impose unnecessary cost. Accordingly, for this incumbent application process, we propose to grant NYCTA's request to waive frequency coordination requirements for one year following the effective date of those rules. However, we propose that after the one-year deadline, an application from an incumbent licensee to supply the required database information would be treated as any other application for a new license or modification, *i.e.,* it would require frequency coordination. We seek comment about whether the status of a license should become secondary if the incumbent licensee does not meet the one-year deadline.

Finally, we decline to propose that incumbent licensees modify their licenses to conform to the new proposed rules and band plan. We agree with commenters such as Region 8 and King County/Seattle that such action would be unduly burdensome and inequitable to incumbent licensees, which already use the band for mission critical public safety operations. Instead, we propose to grandfather existing licensees from having to make any technical modifications to conform to the new rules and band plan, other than

providing more sufficient data as we discussed above, as of the effective date of new rules adopted in this proceeding. However, applications from incumbent licensees submitted more than one year after the new rules are in effect would be subject to the new proposed rules and band plan.

Regional Planning

Section 90.1211(a) of the Commission's rules provides that each RPC region may submit a plan with guidelines to be used for sharing spectrum in the 4.9 GHz band. The rules list elements to be included in regional plans and provide instructions for the plan's modification. Although the Commission originally set a deadline for all RPCs to submit 4.9 GHz regional plans, it subsequently decided to make plan submission voluntary and stayed the deadline. To date, only 10 out of 55 RPC regions have submitted 4.9 GHz regional plans. In the *Fifth FNPRM,* the Commission sought comment on whether it should lift the stay and amend § 90.1211 to require Regional Plans to cover permanent fixed links and base stations, as well as mobile and temporary fixed links.

NPSTC's Plan states that ''a single national plan for 4.9 GHz will meet most regions' needs,'' but ''some regions will need some different parameters to better meet needs of users in their regions. NPSTC proposes to allow RPCs to file amended regional plans specific to 4.9 GHz to reflect regional considerations, including a required showing of need, within 120 days after the Commission adopts new rules for the band. Several commenters support RPC involvement in the 4.9 GHz band.

Discussion. We believe that RPCs should play an integral role in shaping use of the 4.9 GHz band through regional planning. In this connection, we propose to afford RPCs the flexibility to file new and amended regional plans for Commission review and approval to reflect their region-specific needs or considerations as supported by a showing of need. Alternately, RPCs would have the option to default to the national rules without regional variation by taking no action. We seek comment on this proposal, and on how to implement regional variations.

NPSTC recommends that RPCs be able to make region-specific changes in the following four areas: (i) Enabling additional channel aggregation; (ii) incorporating an additional channel designated for specialized use; (iii) placing limits on the use of P–P links in urban areas or imposing more stringent antenna requirements or other technical parameters to allow greater channel reuse; and (iv) in rural areas, allowing higher radiated power for longer path lengths and non-line of sight paths. We tentatively disagree with the NPSTC Plan's proposals for item (i) because we propose to allow 40 megahertz channel aggregation, and for item (iv) because we believe that the upper equivalent isotropically radiated power (EIRP) limits should be codified in our rules rather than left to the discretion of the RPCs. We propose to allow regional plans to be submitted for Commission approval that include variations for items (ii) and (iii) as well as for polarization. In lieu of item (i), we propose to allow RPCs to limit aggregations to 20 megahertz as discussed above. We also propose to limit the ability of RPCs to restrict non-public safety licensing eligibility to a greater degree than is provided in the Commission's rules. In general, we believe that providing these areas in which a regional plan can deviate from the national plan, combined with the overall flexibility of the band plan we propose, will enable regions to meet most needs of their users without threatening investments in existing deployments. Because we cannot foresee all areas in which RPCs may need flexibility, we propose to allow RPCs to request changes outside these areas pursuant to a waiver request. We are mindful that regional variations add a challenge to frequency coordination, but we believe that frequency coordinators have the tools to keep track of these variations. We seek comment on relative costs and benefits arising from this approach, which would not change the status of regional plans as optional.

We seek comment on when RPCs should be required to submit regional plans. Comments on this issue were mixed, with suggested deadlines of 180 days, 240 days, and 12 months after final rules are effective. Considering the resource constraints on RPCs, we propose a deadline of six months after the effective date of final rules for each RPC to notify the Commission either that it intends to file a regional plan or that the region will default to the general rules, and a deadline of one year after rules adopted in this proceeding become effective for the filing of regional plans. Prior to Commission acceptance of any regional plan, we propose to allow new applications for 4.9 GHz licenses to be filed consistent with updated general rules. These licenses would be grandfathered for the duration of the license period. We would lift the current stay on § 90.1211(a) once the proposed rule modification becomes effective. We propose to continue to accept regional plans and amendments after the one-year deadline for the benefit of those RPCs that lack the resources to file timely regional plans or are not yet formed, but the purpose of the deadline is to provide a goal to commence licensing based on regional plan considerations. The Public Safety and Homeland Security Bureau would place any submitted regional plans on public notice for comment. With regard to Plan Amendments, we seek comment on establishing a streamlined process for staff review of such modifications, including defining ''major'' and ''minor'' plan modifications as defined by § 90.527(b) of the rules. We seek comment on these proposals and solicit alternative suggestions, especially from the individual RPCs. We seek comment on any burdens that the regional plan filing deadline may place on small entities.

Finally, we decline the NPSTC Plan's recommendation to permanently waive the existing requirement to obtain concurrence from adjacent regions for plan amendments. The NPSTC Plan makes no mention of the existing adjacent region coordination requirement for initial regional plans, and we do not see why regional plan amendments should not also be subject to adjacent region review. This adjacent region review process for plan amendments has worked in the 700 MHz and 800 MHz bands, and we do not believe the process which is currently in place is unduly burdensome on RPCs for the 4.9 GHz band. We seek comment on whether adjacent region review requirements would place undue burdens on small entities.

Technical Standards

In the *Fifth FNPRM,* the Commission sought comment on whether to adopt technical standards for 4.9 GHz band equipment. While acknowledging that the Commission previously had declined to mandate such a technical standard, the Commission sought comment on using IEEE 802.11 as a potential standard solution, given the standard's worldwide availability and flexibility in supporting various applications. Some commenters to the *Fifth FNPRM* assert that mandatory technical standards would inhibit technological development in the band, restrict local flexibility and control, and render existing equipment obsolete. Other commenters contend that standards would promote national interoperability and lend certainty to the marketplace for 4.9 GHz equipment.

A number of these commenters express specific support for an 802.11-based standard.

Discussion. Since the Commission adopted service rules for the 4.9 GHz band in 2003, the 4.9 GHz band has not fostered a market for diverse technology or inexpensive equipment, which in turn has led to underutilization and a slow influx of users. In general, the Commission has favored technology-neutral rules and has avoided adoption of mandatory standards, a model that has worked in many spectrum bands. However, the record in this proceeding suggests that some public safety users may desire greater certainty regarding technical standards to stimulate investment in the band. While we tentatively conclude that we should not adopt mandatory technical standards for the 4.9 GHz band and seek comment on this view, we seek comment on how to encourage voluntary implementation of technical standards for equipment in the band that can provide certainty for public safety users while also providing appropriate incentives for manufacturers to develop innovative and cost-effective equipment that will encourage interoperability, discourage fragmentation, and reduce equipment costs through higher economies of scale. Would a voluntary industry standard/framework that would not be promulgated in our rules be appropriate and preferable to incorporating such a standard (or any other) in our rules? Are there industry standards available in the 4.9 GHz band, and if not, what is the likelihood that applicable standards could be extended to the 4.9 GHz band? What would be the relative cost and benefit of different voluntary standards for high-power and low-power systems?

Point-to-Point and Point-to-Multipoint

Until 2009, permanent fixed P–P and P–MP stations in the 4.9 GHz band were secondary to base, mobile, and temporary fixed operations. In 2009, the Commission permitted licensing of permanent fixed P–P and P–MP stations that deliver broadband services on a primary basis, while those stations that deliver narrowband traffic remain secondary to other operations in the 4.9 GHz band. In the *Fifth FNPRM,* the Commission sought comment on whether to license all permanent fixed P–P stations on a primary basis, regardless of whether they support broadband or narrowband traffic, or whether permanent fixed P–MP stations not delivering broadband service should remain secondary.

Discussion. Secondary status requires the user to accept the risk of interference and to cease operation if it causes interference to a primary licensee. The supporting commenters persuade us that primary status for P–P and P–MP links that carry or support narrowband traffic would resolve this risk and increase usage of the 4.9 GHz band because it would give potential users confidence to invest in the band. Given the divided comment record on primary status for narrowband P–P and P–MP links, we propose to allow licensees to use individual 1–MHz bandwidth Channels 14–18 for permanent fixed P–P and P–MP operations on a primary basis, while existing permanent fixed P–P and P–MP operations on individual 1–MHz bandwidth Channels 1–5 would remain secondary, with no such further licensing allowed on those channels due to the proposed aeronautical mobile and robotic designation. We seek comment on this proposal, including its relative costs and benefits. Under the status quo, any competing public safety organization in dense urban areas could obtain secondary licenses for P–P and P–MP links on channels 14–18 with no obligation to protect each other from interference. Accordingly, one potential cost of a proposal to license these links on a primary basis is that it could increase the difficulty of competing public safety organizations in dense urban areas to obtain primary licenses for base, mobile, and temporary fixed operations in channels 14–18 because primary users are entitled to interference protection and cannot be licensed with overlapping channel assignments and areas of operation as secondary use may allow. How likely is this to occur, and what would be the cost of a work-around?

The NPSTC Plan recommends that applications for P–P licenses include a showing as to the need for the bandwidth requested, to address the potential of P–P links to cause interference. At this time, we do not propose to impose such a requirement, which no other commenter has suggested, because the record does not contain objective benchmarks for correlating various uses with bandwidth needs. We have found that no evidence of P–P interference in the record, and we invite commenters to submit any such evidence. Further, we believe that technical rule changes we propose below in the Power Limits section may reduce interference potential by producing more directional P–P links. We seek comment on our view and on these concerns.

Next, in order to limit ''temporary'' links to truly temporary uses, we propose to adopt the NPSTC Plan's recommendation that temporary P–P links may only be operated for thirty days maximum over a given path in a one-year period. Any application for longer operation would require a showing why longer duration is needed and how the link is supporting public safety protection of life and property. We seek comment on whether the number of days should be reduced or increased and the reasons therefor. We seek comment on the relative costs and benefits of the limitation proposed here, as well as any alternate proposals. We solicit alternative suggestions and solicit comment on burdens that a timeframe limitation on temporary P–P links would place on small entities.

Finally, we decline to consider a request from the comment record that the band be used only for fixed uses. The band supports substantial mobile use, and it would be contrary to the public interest to force such operations to relocate from the 4.9 GHz band or cease operation. We believe that with the regional planning process combined with frequency coordination, the goal of increased density of fixed link deployment can occur with rule changes regardless of mobile presence. We seek comment on this tentative conclusion.

Power Limits

The 4.9 GHz rules contain power output limits that depend on the channel bandwidth for both low power and high power transmitters. High power P–P and P–MP links may use directional antennas with gains greater than 9 dBi and up to 26 dBi with no reduction in conducted output power, but if antennas with a gain of more than 26 dBi are used, the maximum conducted output power and peak power spectral density must be reduced by the amount in decibels that the directional gain exceeds 26 dBi. The Commission imposed the antenna gain rule ''in order to avoid interference from fixed operations to mobile operations.''

In the *Fifth FNPRM,* the Commission sought recommendations for an effective radiated power (ERP) limit for high power, permanent and temporary fixed transmitters, and whether to impose a maximum ERP limit on point-to-point links. Going forward, we will discuss radiated power levels in the 4.9 GHz band in terms of EIRP, rather than ERP, because antenna gains in the 4.9 GHz band rules are conventionally specified in terms of gain relative to an isotropic reference (dBi). To make point-to-point use in the band more efficient, the Commission also sought comment on whether it should establish a different minimum gain for P–P transmitting antennas and, if so, what value of gain

would be appropriate and what power reduction, if any, should be required.

The NPSTC Plan does not address ERP limits, but it notes that § 101.143 of the Commission's rules specifies a formula for reducing the maximum EIRP for short path lengths and proposes ''that the frequency coordinators use a similar reduction in maximum EIRP for short path lengths with formulas developed based on transmit powers allowed in this band.'' The NPSTC Plan further recommends that for P–P links an antenna with a minimum gain of 26 dBi, a maximum of 5.5 degree beamwidth and a minimum 25 dB front-to-back ratio be required. The NPSTC Plan also recommends that frequency coordinators be allowed to impose tighter specifications for the antenna if that allows assignment of a channel that otherwise would cause interference. NPSTC states that equipment using ''multiple modulation rates and/or MIMO [multiple-input and multiple-output] antenna technologies'' is inefficient and proposes that ''they normally not be allowed in the band.'' NPSTC recommends that requests for higher EIRP levels only be granted under waiver and receive full coordination so that both frequency coordinators and RPCs can comment.

The APCO Report argues for ''increasing the size of the antennas supporting 4.9 GHz operations.'' APCO states that ''larger directional antennas (*i.e.* 4′ diameter and above) have more discriminatory ''off-path'' antenna patterns and FB (Front-to-Back) ratios which allow the coordinator to assign frequencies closer together and permit more systems to co-exist, interference-free, within a given frequency band.'' APCO also contends that ''there are cases where a larger antenna may allow the coordinator to assign a frequency to a system where a smaller antenna may not have an efficient enough antenna pattern.''

Discussion. We propose to allow P–P transmitting antennas to operate with a minimum directional gain of 26 dBi, maximum 5.5 degree beamwidth and minimum 25 dB front-to-back ratio. Antenna physical size, or area, is related to antenna gain. Although the rules do not contain restrictions on physical antenna size, we believe this proposal will enable users to deploy larger directional antennas, as recommended in the APCO Report, and to produce narrower beam widths and more directional P–P links, which should enable co-channel users in congested areas to place links closer together and achieve greater frequency reuse. Moreover, the higher gain would increase the EIRP so that P–P links can cover longer distances, which could save users the expense of deploying multiple, low EIRP links. Further, the record indicates that several low cost antennas that meet these requirements are already available. We seek comment on the relative costs and benefits of this proposal. We invite commenters to provide additional information about these antennas and associated costs in the record and we seek comment on the levels of directional antenna gains that licensees are using today. We also seek comment about burdens that a change to the antenna gain rules would place on small entities, notwithstanding that we propose to grandfather existing P–P and P–MP installations from having to replace antennas.

We seek comment on whether the rules should contain a maximum EIRP limit for directional links. Although the NPSTC Plan proposes no maximum EIRP, three commenters suggest power levels equivalent to maximum EIRP levels of 65.15 dBm for P–P and 55.15 dBm for P–MP to ''promote the use of the band for longer range communications . . . , particularly in rural areas.'' Accordingly, we seek comment on these EIRP limits. Since we noted above that the upper power limits need to be codified in the rules, we seek comment on whether these proposed power limits are adequate to meet the needs of regions whose users would deploy links with long path lengths in rural areas. We also seek comment on whether such an increase in maximum power levels for directional links creates any additional interference concerns and how it might affect the ability to coordinate additional links. Similarly, what effect might such an increase have on the ability for continued mobile operations in the band? We seek comment on whether emission mask M is sufficient, or whether a tighter emission mask should be imposed for these higher power operations. We seek further comment on other power suggestions in the record and how they would fit with the above proposals.

Finally, we decline to propose restrictions on multiple modulation rates and MIMO antenna technologies as proposed by the NPSTC Plan. We agree with the City of New York that ''Multiple Input Multiple Output (MIMO) technology is a key element of both the 802.11n standard and LTE standards. Rather than being less spectrally efficient, it is more so as it provides for increased throughput and range.'' Similarly, multiple modulation rates are more spectrally efficient and offer licenses additional flexibility in the planning and operation of their systems.

Polarization

The *Fifth FNPRM* sought comment on requiring P–P links to use a specific polarization, *e.g.,* horizontal or vertical, to reduce potential interference to other links or to portable or mobile devices. The Commission sought comment on the costs of changing an antenna's polarization and whether polarization diversity would increase throughput.

Discussion. Given the mixed comment record, we decline to propose any polarization requirements in our rules. However, we still believe that polarization can be a tool to increase density of P–P links in a given area and to address cases of actual interference between two or more P–P links. We note that side-by-side co-channel P–P links with orthogonal (opposite) polarizations could operate with minimized interference because each receive antenna would reject signals of the opposite polarization. We are also encouraged that dual polarization together with polarization multiplexing can increase capacity in a P–P link, as Cambium suggests. As discussed above, we propose to allow regional plans submitted for Commission review pursuant to § 90.1211 to propose any polarization schemes for new applications within their regions as necessary to maximize frequency reuse, manage interference, and increase throughput. As part of the application frequency coordination process, frequency coordinators would be able to recommend a particular polarization for a proposed P–P link in those regions. We seek comment on this proposal.

Deployment Reports, Construction Deadlines

The *Fifth FNPRM* sought comment on whether to require 4.9 GHz licensees to file periodic deployment reports to better inform the Commission about usage of the band. The Commission indicated that reports could include information such as status of equipment development and purchase, including number of devices and users; site development, including use of existing towers; deployments and upgrades (commencement and completion), including site information and location; and applications in development or in use. The Commission also sought comment on reporting frequency.

Discussion. Although a deployment report requirement had some support in the record, we agree with the opposing comments regarding burdens on licensees and decline to propose requiring deployment reports. In addition to imposing a burden, such reports would be superfluous given our

database proposal discussed above, in which existing licensees would file certain additional information on their operating parameters.

However, we propose to establish a one-year construction deadline for all 4.9 GHz licensees, with a corresponding construction reporting requirement. The current rules impose an 18-month construction deadline only on fixed P–P stations that are licensed on a site-by-site basis, and no construction deadline for base and temporary fixed stations. We believe that shortening the construction period to one year for all 4.9 GHz licenses will lead to more timely use of the spectrum and reduce the possibility of spectrum warehousing. Accordingly, we propose to require all 4.9 GHz geographic licensees to place at least one base or temporary fixed station in operation within 12 months of license grant and file a standard construction notification with the Commission. We also propose to reduce the construction period for fixed point-to-point stations from 18 months to 12 months. These proposed rule changes will also harmonize the construction deadlines for the 4.9 GHz band with the deadlines of § 90.155, which is the analogous rule for the majority of part 90 radio services. We note that we have received no objections to this construction deadline change. We seek comment on these proposals, on their relative costs and benefits, on the burdens that the proposed construction deadline would place on small entities, and on alternative solutions that would achieve the same goal.

Eligibility, Shared Use, and Other Alternatives

Currently, only entities providing public safety services are eligible for licenses in the 4.9 GHz band. Non-public safety entities—including CII entities—may use the 4.9 GHz spectrum by entering into sharing agreements with eligible public safety licensees, but only for ''operations in support of public safety.'' In light of the limited use of the band to date by public safety, the *Fifth FNPRM* sought comment on whether expanding eligibility to non-public safety users might lead to increased use and reduction in equipment costs that would benefit public safety. Specifically, the Commission sought comment on whether CII entities should be eligible to hold primary 4.9 GHz licenses, thus removing the requirement for a sharing agreement, and also whether the band should be opened to commercial users on a secondary or non-interfering basis subject to a shutdown mechanism to enable priority access by public safety entities. In response to the *Fifth FNPRM,* the NPSTC Plan proposed to extend primary 4.9 GHz eligibility to CII. More recently, other *ex parte* filers have recommended various secondary spectrum sharing approaches combined with maintaining priority status for public safety in the 4.9 GHz band.

In this *Sixth FNPRM,* we seek to further discuss these alternative eligibility and spectrum sharing approaches and other alternatives for the band. We seek comment on four specific alternatives outlined below, and on whether the four alternatives or elements thereof could be combined. We also solicit comment on any other sharing approaches that would meet the Commission's goals for the band.

Extending Eligibility to CII

The NPSTC Plan proposes to expand eligibility to afford CII co-primary status with public safety in the 4.9 GHz band and allow CII entities immediate access to two five-megahertz channels (Channels 6 and 7). On the remaining channels in the band, NPSTC proposes to preserve public safety's licensing priority for three years, but would allow CII to seek access on a notice basis. Under the proposed notice procedure, a CII entity's application to use unoccupied channels would be put on public notice, and any public safety entity in the same geographic area as the CII entity's planned system would have 30 days to file an application for the same channels, in which case the public safety applicant would prevail. This notice process would expire after three years after the Commission's rules become effective, at which point public safety and CII would have equal access to all channels in the band with no required notice.

The majority of commenters responding to both the *Fifth FNPRM* and the NPSTC Plan support expanding 4.9 GHz band eligibility to CII entities. APCO and FCCA/IAFC/IMSA assert that CII eligibility would enhance interoperability between utilities and public safety agencies during and immediately following major emergencies, although APCO cautions that CII use should be ''carefully monitored to ensure that public safety needs are considered in every potential conflicting filing.'' The Utilities Telecom Council (UTC) states that CII primary eligibility ''could provide capacity and coverage for smart grid and other applications . . . [and] would promote investment in and more effective use of the spectrum.''

Some public safety commenters oppose direct licensing of CII entities and advocate retaining the requirement that CII entities may only use the 4.9 GHz band pursuant to sharing agreements with public safety licensees. In response, Southern Company contends that ''the current eligibility rules for the 4.9 GHz band do not correlate with marketplace or political realities,'' because CII entities are ''understandably reluctant to enter agreements whereby their investment in infrastructure, and their use of a vital communications resource, could be rendered worthless at any time, including when that resource is needed most.''

Some commenters advocate expanding CII eligibility to include additional categories of potential users. The Enterprise Wireless Alliance (EWA) proposes extending 4.9 GHz band eligibility to ''all private internal systems'' that ''have defined areas of operation not necessarily focused on population centers, often conducted in a campus-type environment that can be coordinated with public safety usage.'' The Alarm Industry Communications Committee (AICC) argues that alarm companies should have primary access to the 4.9 GHz band in order to allow them ''to more efficiently and rapidly gather and forward to PSAPs information about emergencies.''

Discussion. We seek comment on whether offering CII co-primary status with public safety is likely to create incentives for increased investment in the 4.9 GHz band. The Commission has recognized that railroad, power, and petroleum entities use radio communications ''as a critical tool for responding to emergencies that could impact hundreds or even thousands of people.'' Extending eligibility to CII could encourage collaborative investment by public safety and CII users of the 4.9 GHz band to improve response to emergencies that affect both public safety and critical infrastructure. We seek comment on this approach, including its potential relative costs and benefits.

We also seek comment on whether eligibility for CII entities should be conditioned on using the band to provide ''public safety services'' as that term is defined in Section 337(f)(1)(A) of the Communications Act of 1934, as amended. For example, API requests that CII entities be permitted to use the band for any purpose, not just in support of public safety. Would eliminating the requirement that the band be used for ''public safety services'' by CII users increase use of the band, lowering equipment costs and facilitating the other benefits of CII access to the band? Or would it unduly

increase congestion? Considering the public safety focus of the 4.9 GHz band, should we limit CII use of the 4.9 GHz band to communications related to the protection of life, safety, and property, as opposed to general business purposes? If we maintain the requirement, how should the Commission ensure compliance by CII users (and what are the costs of doing so)? Given public safety's relatively modest use of 4.9 GHz spectrum to date, we think there is sufficient remaining spectrum in the band to accommodate both expanded use by public safety and CII co-primary use. Stated otherwise, we think the benefits of co-primary use of the band by both CII and public safety can be realized at slight or no cost to public safety. We seek comment on this characterization. Is there reason to elevate public safety communications in the band over other uses? If so, would preferential algorithms built into equipment ensure priority of public safety communications? How would that priority be achieved? Would such priority be sufficient to ensure that public safety traffic would not be interfered with? We seek comment on affording public safety priority over other users and how priority would be achieved.

If we grant co-primary eligibility to CII entities without the need for a sharing agreement with a public safety entity, we seek comment on NPSTC's proposal to provide CII immediate, co-primary access to Channels 6 and 7 during the first three years, to establish a notice procedure for CII access to the remainder of the band during the three-year period, and to open up the entire band to CII thereafter. Should we consider alternative access arrangements, such as providing CII immediate access to Channels 12 and 13, which could be coupled with access to narrowband Channels 14–18 to create 15 megahertz of contiguous spectrum for CII to access on a co-primary basis? Should we exclude Channels 1–5 from CII eligibility in light of our proposal to dedicate this segment to public safety aeronautical mobile and robotic use? We seek comment on these options and solicit any alternative suggestions.

We in turn seek comment on extending 4.9 GHz band co-primary eligibility to all private internal systems, as EWA requests. Would doing so be consistent with our core goal of supporting critical public safety needs? Similarly, we seek comment on extending primary eligibility to alarm companies as advocated by AICC. Does the fact that the Commission's recent review of ULS in another proceeding suggesting that certain frequencies designated for central alarm operations may be underutilized affect how we should approach this request? Finally, we note that the Commission's general approach to making spectrum available in recent years has leaned toward flexible use rather than allocations to specific industries. We seek comment on how granting CII entities eligibility for co-primary status is consistent with this approach. We also ask how CII entities' need for co-primary use of this band can be differentiated from the needs of other critical and safety-related industries that may seek access to this band in the future.

Leasing

In the 2003 *4.9 GHz Third Report and Order,* the Commission allowed non-public safety entities engaged in providing public safety-related services to be licensed in the 4.9 GHz band to support public safety operations. In 2004, the Commission permitted public safety licensees with ''exclusive spectrum rights'' to lease their spectrum to other public safety entities eligible for such a license authorization and to entities providing communications in support of public safety operations. Based on the record at that time, the Commission declined to permit public safety licensees to lease 4.9 GHz spectrum for commercial or non-public safety operations. Specifically, the Commission noted that commenters expressed concern that such leasing could face statutory barriers or result in abuse without the implementation of regulatory safeguards. In the *Secondary Markets Order,* the Commission also noted that allowing such leasing could be premature given the then-nascent state of ''interruptible use'' technology that would enable public safety licenses to immediately reclaim the use of any leased spectrum for public safety emergencies.

Discussion. In this *Sixth FNPRM,* we seek to establish new licensing and service rules for the 4.9 GHz band that will spur investment and innovation while furthering public safety use of the band. We seek comment on whether these objectives could be facilitated by expanding the leasing alternatives available to public safety in the band. In particular, should we remove the current limitation and allow public safety licensees that have obtained exclusive spectrum rights in the 4.9 GHz band to lease spectrum capacity to CII or to commercial entities generally? Would such expanded leasing flexibility stimulate investment in equipment and networks that would benefit public safety and further our objectives for increased use of the band? Would such leasing opportunities present public safety entities with new potential revenue streams that could be used to increase investment in NG911 operations or to purchase new 4.9 GHz equipment? What rule changes, if any, would best facilitate bringing the economies of scope and scale that come with commercial use of a band to this public safety spectrum? How would a leasing alternative lead to increased use of the band compared to the current environment, where non-public safety entities can to enter into sharing agreements with public safety licensees? What are the relative costs and benefits of expanding leasing alternatives?

We also seek comment on how best to ensure that public safety would retain priority access to 4.9 GHz spectrum in any commercial leasing framework. As noted above, the Commission cited a dearth of technology in 2004 that would support ''interruptible'' spectrum leasing. In light of the significant technological advances that have occurred since then, does technology now exist that would enable public safety to interrupt other spectrum users and reclaim leased spectrum capacity in emergencies? Should non-public safety entities that lease spectrum capacity have primary status because they entered agreements with specific public safety licensees? If so, how would public safety priority function?

As noted above, in the *Secondary Markets Order* the Commission cited to comments expressing concern that the Communication Act might be a barrier to allowing public safety entities to lease spectrum that had been designated for public safety for non-public safety operations. Those comments suggested that because Section 337 of the Communications Act of 1934 defines ''public safety services'' as services that ''are not made commercially available to the public by the provider,'' the Commission could be limited in its ability to allow non-public safety services on bands designated for public safety services. However, Section 337's proscription on commercial operations is expressly limited to 24 megahertz of spectrum in the 700 MHz band, and there is no equivalent statutory limitation on the 4.9 GHz band. Section 90.1203 of our rules, which governs eligibility for 4.9 GHz licenses, incorporates the requirements and conditions set forth in § 90.523 of our rules, which in turn implements Section 337 of the Act, and provides that applications in this band are limited to operations in support of public safety. The Commission tentatively concludes that it has authority to modify § 90.1203 to allow public safety licensees to enter

into leases for non-public safety or commercial uses in the 4.9 GHz band. We seek comment on this tentative conclusion. Are there any other potential jurisdictional barriers to adopting the rules proposed here?

If we authorize expanded leasing by public safety in the 4.9 GHz band, should there be conditions or limitations on use of leased spectrum or expenditure of leasing revenues to safeguard against potential abuse? For example, should use of leased spectrum be limited to communications in support of public safety or should all communications be allowed regardless of whether they have a public safety nexus? Can or should we require public safety licensees that receive leasing revenues to invest such revenues solely for public safety purposes, *e.g.,* for procurement of public safety equipment or maintenance and operational costs of the network? Would such a requirement be consistent with the Miscellaneous Receipts Act? Are there provisions of state or local law relating to use of funds by local public safety entities that the Commission should take into consideration here? How would compliance with such a requirement be audited and enforced?

We seek comment on the relative costs and benefits of a commercial-leasing options vis-à-vis the CII co-primary option discussed above. Which option would bring the greatest innovation to the 4.9 GHz band? Which option would best facilitate the introduction of new, lower cost equipment? Which option would best empower public safety users—the case-by-case leasing to commercial entities where public safety users must sign off on each use or the ability of CII users to gain co-primary access to the spectrum without further public safety input? In short, which of these options would best serve our goals in increasing shared use of this band at the lowest cost? As noted above, given public safety's relatively modest use of 4.9 GHz spectrum to date, we think that allowing leasing would not impose any cost on public safety. Stated otherwise, we think the benefits of allowing more efficient spectrum use through leasing can be realized at no cost to public safety. We note that there are potential revenue streams from leasing, further supporting our judgement that allowing leasing would be produce benefits that exceed relative costs. We seek comment on this characterization.

Two-Tiered Sharing on a Secondary Basis

In the *Fifth FNPRM,* the Commission sought comment on whether to open 4.9 GHz band eligibility to commercial users on a secondary or non-interfering basis, while ensuring priority access for public safety entities by means of a sharing mechanism, such as dynamic access control based on a database similar to that used for TV white spaces devices. In response, some commenters support extending eligibility to commercial entities on a secondary basis. Carlson, AICC, Spectrum Bridge, SSC, and WISPA suggest that adopting an intelligent, dynamic database system as the sharing mechanism could allow non-public safety to use the 4.9 GHz band on a secondary basis. The APCO Report recommends that the Commission consider ''build[ing] upon the 'white space' model and apply[ing] it to the 4.9 GHz arena to spur development by increasing the potential customer base, including within the CII segment.'' APCO recommends that the Commission study ''[a]n innovative approach that incorporates essential features such as frequency coordination, with newer spectrum management tools that could expand the user base while preserving reliable access for public safety.''

However, many public safety commenters oppose opening the band to commercial users, even on a secondary basis. These commenters express concern that because public safety generally requires greater lead time than commercial entities to secure funding to construct communications systems, commercial operations could foreclose public safety use and increase the risk of interference and congestion. Commenters also express skepticism about the feasibility of a using a dynamic database as a sharing mechanism. FCCA/IMSA/IAFC argue that ''white space-style databases are not appropriate for the 4.9 GHz band'' because they rely on equipment that employs geo-location or similar technologies, and ''requiring 4.9 GHz devices to incorporate geo-location or similar capabilities will unnecessarily impede the development of equipment for the band.'' Southern similarly ''does not believe the database paradigm used for TV White Spaces . . . devices would be appropriate for the 4.9 GHz band,'' citing the risk to public safety that could be caused by ''loss of critical communications service due to database errors, malfunctions of the coordination system, or loss of connectivity with the database.''

Discussion. As a third option, we seek comment on the feasibility of a two-tiered sharing approach, in which Tier 1 would consist of primary licensees in the band (including all incumbent users), while Tier 2 would allow other non-public safety users to access the band on a secondary basis, with safeguards to ensure priority and interference protection for Tier 1 operations. We seek comment on potential mechanisms that could facilitate two-tiered sharing in the 4.9 GHz band while protecting primary users.

For example, could we implement Tier 2 secondary access to the 4.9 GHz band using frequency coordination and licensing procedures similar to those we are proposing for primary licensing? The public safety community has long relied on frequency coordination in other spectrum bands to protect mission-critical communications from interference. While this system has worked well in other bands, frequency coordination in the 4.9 GHz band would typically take place before deployment and does not take into account the dynamically changing environment of real-time spectrum usage. We seek comment on whether a frequency coordination approach to Tier 2 secondary use would provide sufficient flexibility to support dynamic spectrum use while protecting Tier 1 users. Would real-time coordination be feasible if we required Tier 2 users to provide digital identification and/or geo-location so that Tier 1 users could readily identify potential sources of interference to their systems? We seek comment on relative costs and benefits that a digital ID and/or geolocation requirement on Tier 2 users would have, especially for Tier 2 small businesses.

We also seek comment on the feasibility of developing an automated database system to enable dynamic Tier 2 secondary use of the 4.9 GHz band while protecting Tier 1 operations. We acknowledge the concerns raised by commenters that ''white-spaces'' databases previously developed for commercial bands might not provide sufficient assurance of real-time protection for mission-critical public safety operations. We seek comment on what capabilities an automated system would need to support the public safety requirements of the 4.9 GHz band. Should the database be centralized or distributed? What would it cost to design, build, and operate such a system, and who should be responsible for such costs? What information would Tier 1 and Tier 2 users need to enter and update in the database to facilitate dynamic spectrum sharing? What would be the cost and burden of providing such information? How would an automated system communicate with users' devices to help minimize interference and facilitate registration, coordination, and dynamic access?

What capabilities would be required to identify potentially interfering Tier 2 users in real time and to direct them to move to a non-interfering channel or to shut down? We seek comment on these issues and on alternative models for spectrum sharing that would achieve these goals. Beyond the upfront cost of designing, building and operating the automated database system, and recurring database maintenance costs—both necessary to enable dynamic Tier 2 secondary use—such dynamic spectrum sharing would appear to impose few costs on public safety because it would retain primary access to the spectrum as needed. These costs would be the costs of entering and updating information to the automated database. We seek comment on whether the benefits to secondary users would outweigh the upfront, recurring, and database entry relative costs, and any other appreciable costs that we may not have taken into account.

Redesignation of the Band

As this spectrum has been underutilized, we request comment on redesignating the 4.9 GHz band, wholly or partially, to support commercial wireless use. Are the bases for the Commission's decision in 2002 to allocate the entire band for public safety purposes still valid, or does the public interest now call for a change? For example, would the public interest be best served if this spectrum could be used for commercial applications, such as 5G, or would it be better to strike a balance between public safety and commercial uses? What are the relative costs and benefits of a commercial use of this spectrum as weighed against the band plan we propose above or the sharing use alternatives on which we seek comment? If only a portion of the band were to be redesignated, how should the band be divided between public safety and commercial use? If any or all of the spectrum is redesignated for commercial wireless purposes, should the Commission consider auctioning the redesignated spectrum, making licenses available on some other basis, or authorizing the spectrum for unlicensed use under part 15 of the Rules? We seek comment on any other alternatives to support commercial wireless use of the 4.9 GHz band. If the band were made available for licensed or unlicensed use, we seek comment on what the technical rules would be appropriate. Specifically, if the band were made available for licensed use, should we apply the power levels, emissions limits, and other technical requirements that are in the existing 4.9 GHz band technical rules, the Citizen's Broadband Radio Service (CBRS) as reflected in part 96 subpart E, or the technical rules for the AWS–3 spectrum as reflected in part 27 for the 1710–1780 MHz and 2110–2170 MHz bands? The CBRS rules assume time division duplex operation while the AWS–3 rules assume frequency division duplex operation, with each set of rules specifying separate technical requirements for base stations and mobile devices. If the band were made available for unlicensed use, we specifically invite comment on whether we should apply the same technical rules that exist for the U–NII band at 5150–5250 MHz under part 15 subpart E. If the Commission allows commercial use in all or part of the 4.9 GHz band, should it allow both mobile and fixed use? When considering whether to designate all or part of the band for commercial users, should the Commission consider designating the entire band in markets where there are no existing public safety 4.9 GHz facilities? In markets where there are public safety incumbents, should public safety use be limited to those incumbents or should a specified amount of the 4.9 GHz band be reserved for public safety use? If the Commission divides the band into commercial and public safety segments, would it need to establish guard bands or would in-band and out-of-band emission limits suffice to guard against harmful interference? Commenters should address how the loss of opportunities for public safety spectrum use in the 4.9 GHz band might affect congestion in other bands currently allocated for public safety use.

In the event that the Commission redesignates any of the spectrum in the 4.9 GHz band, how should the Commission treat existing public safety systems operating in the band? Should public safety systems simply be grandfathered on their current frequencies? If so, should it be based on the frequencies licensed or those actually deployed and used? If the band is divided into public safety and commercial segments, should public safety licensees be required to relocate their facilities into the public safety segment? In the event the Commission elects to designate the entire band for commercial use, is there alternative spectrum to which existing public safety 4.9 GHz licensees can be relocated? If so, who should pay the relocation cost, *e.g.,* if the Commission decides to auction the redesignated spectrum? Should auction proceeds be used to pay public safety's cost to relocate its systems? We seek comment on the relative costs and benefits of all of these options.

Procedural Matters

Ex Parte Presentations

The proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, see 5 U.S.C. 603, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules addressed in this document. IRFA is set forth in Appendix C of the *Sixth FNPRM.* Written public comments are requested on the IRFA. These

comments must be filed in accordance with the same filing deadlines as comments filed in response to this *Sixth FNPRM* as set forth herein, and they should have a separate and distinct heading designating them as responses to the IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of the *Sixth FNPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

Initial Paperwork Reduction Act Analysis

This document contains proposed new and modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995 (PRA). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we seek specific comment on how we might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

Ordering Clauses

Accordingly, *It is ordered*, pursuant to sections 1, 4(i), 4(j), 4(o), 301, 303(b), 303(g), 303(r), 316, 332, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 154(o), 301, 303(b), 303(g), 303(r), 316, 332, and 403, that this Sixth Further Notice of Proposed Rulemaking is *hereby adopted.*

It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Center, *shall send* a copy of this Sixth Further Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Parts 0, 2, and 90

Organization and functions (Government agencies); Communications equipment; Radio; Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 0, 2 and 90 as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

Authority: Sec. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Section 0.392 is amended by adding paragraph (k) to read as follows:

§ 0.392 Authority Delegated.

* * * * *

(k) Certifies frequency coordinators; considers petitions seeking review of coordinator actions; and engages in oversight of coordinator actions and practices.

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 3. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 4. Section 2.106, the Table of Frequency Allocations, is amended by revising page 41 to read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

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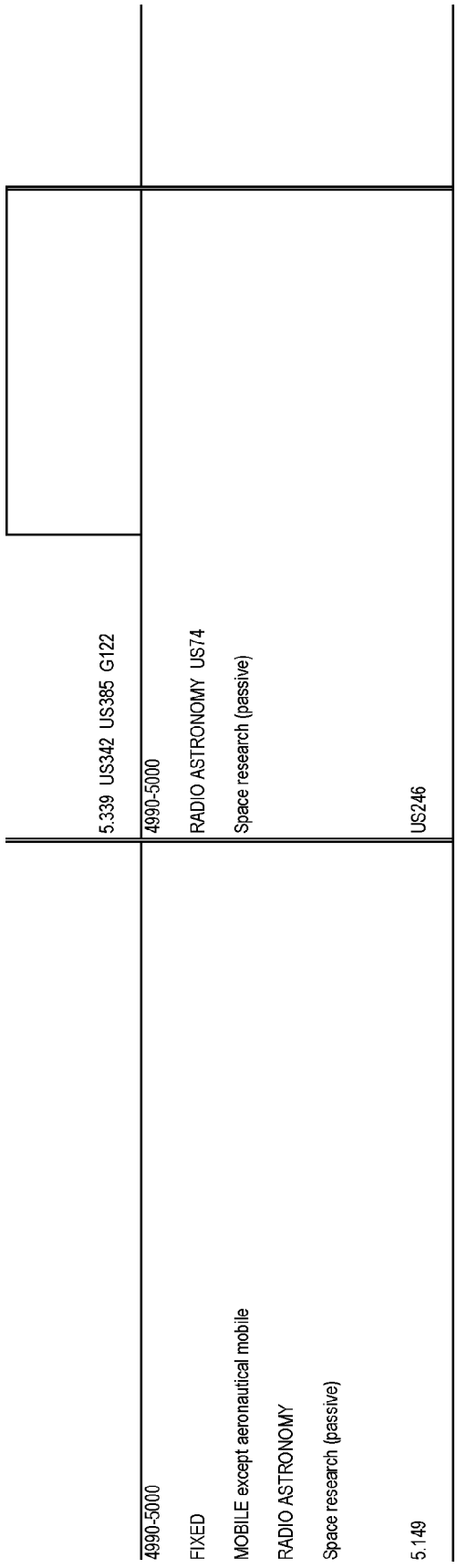
1International Table			United States Table		FCC Rule Part(s)
Region 1 Table	Region 2 Table	Region 3 Table	Federal Table	Non-Federal Table	
(See previous page)	3500-3700 FIXED FIXED-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile Radiolocation 5.433	3500-3600 FIXED FIXED-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile 5.433A Radiolocation 5.433	3500-3550 RADIOLOCATION G59 AERONAUTICAL RADIONAVIGATION (ground-based) G110	3500-3550 Radiolocation	Private Land Mobile (90)
			3550-3650 RADIOLOCATION G59 AERONAUTICAL RADIONAVIGATION (ground-based) G110	3550-3600 FIXED MOBILE except aeronautical mobile US105 US433	Citizens Broadband (96)
3600-4200 FIXED FIXED-SATELLITE (space-to-Earth) Mobile		3600-3700 FIXED FIXED-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile Radiolocation 5.433 5.435	US105 US107 US245 US433	3600-3650 FIXED FIXED-SATELLITE (space-to-Earth) US107 US245 MOBILE except aeronautical mobile US105 US433	Satellite Communications (25) Citizens Broadband (96)
			3650-3700 US109 US349	3650-3700 FIXED FIXED-SATELLITE (space-to-Earth) NG169 NG185 MOBILE except aeronautical mobile US109 US349	

	3700-4200 FIXED FIXED-SATELLITE (space-to-Earth) MOBILE except aeronautical mobile	3700-4200	3700-4200 FIXED FIXED-SATELLITE (space-to-Earth) NG180	Satellite Communications (25) Fixed Microwave (101)
4200-4400 AERONAUTICAL RADIONAVIGATION 5.438 5.439 5.440		4200-4400 AERONAUTICAL RADIONAVIGATION 5.440 US261		Aviation (87)
4400-4500 FIXED MOBILE 5.440A		4400-4940 FIXED MOBILE	4400-4500	
4500-4800 FIXED FIXED-SATELLITE (space-to-Earth) 5.441 MOBILE 5.440A			4500-4800 FIXED-SATELLITE (space-to-Earth) 5.441 US245	
4800-4990 FIXED MOBILE 5.440A 5.442		US113 US245 US342	4800-4940 US113 US342	
Radio astronomy 5.149 5.339 5.443		4940-4990	4940-4950 FIXED MOBILE	Public Safety Land Mobile (90Y)
			4950-4990 FIXED MOBILE except aeronautical mobile 5.339 US342 US385	



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* * * * *

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 5. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), and 332(c)(7), and Title VI of the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, 126 Stat. 156.

■ 6. Section 90.175 is amended by removing paragraph (j)(22) and adding paragraph (k) to read as follows:

§ 90.175 Frequency coordinator requirements.

* * * * *

(k) *For frequencies in the 4940–4990 MHz band:* See § 90.1209 of this chapter for further information.

■ 7. Section 90.1205 is amended by revising paragraph (c) to read as follows:

§ 90.1205 Permissible operations.

* * * * *

(c) Aeronautical mobile and robotic station operations are permitted subject to § 90.1219.

■ 8. Section 90.1207 is revised to read as follows:

§ 90.1207 Licensing.

(a) A 4945–4990 MHz band geographic license gives the licensee authority to operate temporary (1 year or less) fixed stations on any authorized channel in this band within its licensed area of operation. See § 90.1213. A 4945–4990 MHz band license will be issued for the geographic area encompassing the legal jurisdiction of the licensee or, in case of a nongovernmental organization, the legal jurisdiction of the state or local governmental entity supporting the nongovernmental organization.

(1) A temporary fixed station is required to be individually licensed if:

(i) International agreements require coordination;

(ii) Submission of an environmental assessment is required under § 1.1307 of this chapter; or

(iii) The station would affect areas identified in § 1.924 of this chapter.

(2) Any antenna structure that requires notification to the Federal Aviation Administration (FAA) must be registered with the Commission prior to construction under § 17.4 of this chapter.

(b) Subject to § 90.1209, base stations and mobile units (including portable and handheld units) in the 4945–4990 MHz band are required to be licensed on a site-by-site basis. All existing licensees that operate such stations shall seek licenses for such stations in the Commission's Universal Licensing System database by filing new or modification applications within one year after the Public Safety and Homeland Security Bureau and the Wireless Telecommunications Bureau announce by public notice that the database is ready to accept such applications. Any antenna structure that requires notification to the Federal Aviation Administration (FAA) must be registered with the Commission prior to construction under § 17.4 of this chapter.

(c) Permanent fixed point-to-point transmitters and receivers, permanent fixed point-to-multipoint transmitters and fixed receivers in the 4945–4990 MHz band must be licensed individually on a site-by-site basis. All existing licensees that operate such stations shall seek individual licenses for such stations in the Commission's Universal Licensing System database by filing new applications within one year after the Public Safety and Homeland Security Bureau and the Wireless Telecommunications Bureau announce by public notice that the database is ready to accept such applications. Primary permanent fixed point-to-point and point-to-multipoint transmitters must use directional antennas with gains equal to or greater than 26 dBi. All such stations in the 4945–4990 MHz band are accorded primary status.

(d) A 4940–4945 MHz license gives the licensee authority to operate aeronautical mobile or robotic stations subject to § 90.1219 on any authorized channel in this band within its licensed area of operation. *See* § 90.1213. Geographic area licenses and individually licensed stations issued before the effective date of this rule that use spectrum overlapping or within the 4940–4945 MHz band segment are grandfathered.

(e) Existing 4940–4990 MHz band licenses as of the effective date of this rule are grandfathered from revisions to § 90.1215(a)(2).

■ 9. Section 90.1209 is amended by revising paragraphs (b) through (d), and adding paragraph (e) to read as follows:

§ 90.1209 Policies governing the use of the 4940–4990 MHz band.

* * * * *

(b) Each application for a new frequency assignment or for a change in existing facilities must include a showing of frequency coordination. A database of licenses is available at *http://wireless.fcc.gov/uls.* Frequency coordinators and potential applicants should examine this database before seeking station authorization, and make every effort to ensure that their fixed and base stations operate at a location, and with technical parameters, that will minimize the potential to cause and receive interference. Licensees of stations suffering or causing harmful interference are expected to cooperate and resolve this problem by mutually satisfactory arrangements. If licensees are unable to do so, frequency coordinators may adjudicate such matters and recommend solutions to the Commission. The Commission may impose restrictions including specifying the transmitter power, antenna height, or area or hours of operation of the stations concerned. Within one day of making a frequency recommendation, the lead frequency coordinator must send a copy of the application to other certified frequency coordinators. Concurrently, the lead frequency coordinator must send a copy of the application to the adjacent 700 MHz Regional Planning Committee where the signal at the region border exceeds −109 dBW/m2/5 MHz.

(c) Licensees will make every practical effort to protect radio astronomy operations as specified in § 2.106, footnote US385 of this chapter.

(d) Licensees of base or temporary fixed stations must place at least one such station in operation within twelve (12) months of the license grant date, or the license cancels automatically as of the expiration of such twelve-month period, without specific Commission action. Fixed point-to-point and point-to-multipoint stations which are licensed on a site-by-site basis must be placed in operation within twelve (12) months of the grant date or the authorization for that station cancels automatically as of the expiration of such twelve-month period, without specific Commission action.

(e) Temporary fixed point-to-point stations may only be operated for thirty days maximum over a given path over a one-year time frame.

■ 10. Section 90.1211 is amended by revising paragraph (a), (b)(4), and (c) and adding paragraph (d) to read as follows:

§ 90.1211 Regional plan.

(a) To facilitate the shared use of the 4.9 GHz band, each region may submit a plan on guidelines to be used for sharing the spectrum within the region.

(b) * * *

(4) A description of the coordination procedures for permanent fixed point-to-point and point-to-multipoint stations, base stations, temporary fixed stations, and mobile operations. The procedures shall include, but are not limited to, mechanisms for incident

management protocols, interference avoidance, and interoperability.

(c) Regional plans may vary from the band plan in the following areas:

(1) Limit channel aggregation to 20 megahertz bandwidth.

(2) Designate one or more channels for specialized use.

(3) Place limits on the use of point-to-point links in urban areas or impose more stringent limits on antenna gain, maximum conducted output power, power spectral density, or other technical parameters of point-to-point systems relative to the limits of § 90.1215.

(4) Require polarization for point-to-point links.

(d) Regional plans may be modified by submitting a written request, signed by the regional planning committee, to the Chief, Public Safety and Homeland Security Bureau. The request must contain the full text of the modification, and a certification that all eligible entities had a chance to participate in discussions concerning the modification and that any changes have been coordinated with adjacent regions.

■ 11. Section 90.1213 is revised to read as follows:

§ 90.1213 Band plan.

(a) Upon the effective date of this rule, Channel numbers 1 through 5 are aggregated for a channel bandwidth of 5 MHz and may be subsequently licensed for use only in accordance with § 90.1219 of this chapter; any existing operations on these channels prior to the effective date of this rule are grandfathered. Channel numbers 6 through 13 are 5 MHz bandwidth channels and Channel numbers 14 through 18 are 1 MHz bandwidth channels. The following channel center frequencies are permitted to be aggregated for channel bandwidths of 5, 10, 15 or 20 MHz as described in paragraph (b) of this section. Channel numbers 14 through 18 should be used for narrow bandwidth operations and should be used in aggregations only if all other 5 MHz channels are blocked.

Center frequency (MHz)	Bandwidth (MHz)	Channel Nos.
4942.5	5	1–5
4947.5	5	6
4952.5	5	7
4957.5	5	8
4962.5	5	9
4967.5	5	10
4972.5	5	11
4977.5	5	12
4982.5	5	13
4985.5	1	14
4986.5	1	15
4987.5	1	16
4988.5	1	17
4989.5	1	18

(b) The following tables list center frequencies to be licensed for aggregated channels only. A license may contain any combination of bandwidths from aggregated channels provided that the bandwidths do not overlap. The bandwidth edges (lower and upper frequencies) are provided to aid in planning.

(1) 5 MHz bandwidth aggregation:

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4942.5	1 to 5 *	4940	4945
4947.5	6	4945	4950
4952.5	7	4950	4955
4957.5	8	4955	4960
4962.5	9	4960	4965
4967.5	10	4965	4970
4972.5	11	4970	4975
4977.5	12	4975	4980
4982.5	13	4980	4985
4987.5	14 to 18 **	4985	4990

* Licensees for these channels granted after the effective date of this rule may use these channels only in accordance with § 90.1219 of this chapter.

** Licensees should avoid using these channels in aggregations unless all other channels are blocked.

(2) 10 MHz bandwidth aggregation:

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4950	6 & 7	4945	4955
4955	7 & 8	4950	4960
4960	8 & 9	4955	4965
4965	9 & 10	4960	4970

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4970	10 & 11	4965	4975
4975	11 & 12	4970	4980
4980	12 &13	4975	4985
4985	13 to 18*	4980	4990

* Licensees should avoid using these channels in aggregations unless all other channels are blocked.

(3) 15 MHz bandwidth aggregation:

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4952.5	6 to 8	4945	4960
4957.5	7 to 9	4950	4965
4962.5	8 to 10	4955	4970
4967.5	9 to 11	4960	4975
4972.5	10 to 12	4965	4980
4977.5	11 to 13	4970	4985
4982.5	12 to 18*	4975	4990

* Licensees should avoid using these channels in aggregations unless all other channels are blocked.

(4) 20 MHz bandwidth aggregation:

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4955	6 to 9	4945	4965
4960	7 to 10	4950	4970
4965	8 to 11	4955	4975
4970	9 to 12	4960	4980
4975	10 to 13	4965	4985
4980	11 to 18*	4970	4990

* Licensees should should avoid using these channels in aggregations unless all other channels are blocked.

(5) 30 MHz bandwidth aggregation:

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4960	6 to 11	4945	4975
4965	7 to 12	4950	4980
4970	8 to 13	4955	4985
4975	9 to 18*	4960	4990

* Licensees should avoid using these channels in aggregations unless all other channels are blocked.

(6) 40 MHz bandwidth aggregation:

Center frequency (MHz)	Channel Nos. employed	Lower frequency (MHz)	Upper frequency (MHz)
4965	6 to 13	4945	4985
4970	7 to 18*	4950	4990

* Licensees should avoid using these channels in aggregations unless all other channels are blocked.

■ 12. Section 90.1215 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 90.1215 Power limits.

* * * * *

(a)(1) The maximum conducted output power should not exceed:

Channel bandwidth (MHz)	Low power maximum conducted output power (dBm)	High power maximum conducted output power (dBm)
1	7	20
5	14	27
10	17	30
15	18.8	31.8
20	20	33
30	21.8	34.8
40	23	36

(2) High power devices are also limited to a peak power spectral density of 21 dBm per one MHz. High power devices using channel bandwidths other than those listed above are permitted; however, they are limited to peak power spectral density of 21 dBm/MHz. If transmitting antennas of directional gain greater than 9 dBi are used, both the maximum conducted output power and the peak power spectral density should be reduced by the amount in decibels that the directional gain of the antenna exceeds 9 dBi. However, high power point-to-point transmitting antennas (both fixed and temporary-fixed rapid deployment) shall operate with minimum directional gain of 26 dBi, maximum 5.5 degree beamwidth and 25 dB front-to-back ratio. For point-to-point systems, the maximum equivalent isotropically radiated power (EIRP) is 65.15 dBm. High power point-to-multipoint operations (both fixed and temporary-fixed rapid deployment) may employ transmitting antennas with directional gain exceeding 26 dBi. For point-to-multipoint systems, the maximum EIRP is 55.15 dBm. Frequency coordinators may recommend reduction to the EIRP on a case-by-case basis, through reduction of the maximum conducted output power, spectral density, and/or antenna gain. Further, under § 90.1211(c)(3) thorough (4), Regional Planning Committees may recommend alternate lower limits to the allowed antenna gain, maximum conducted output power, or power spectral density of point-to-point systems.

* * * * *

■ 13. Section 90.1219 is added to Subpart Y to read as follows:

§ 90.1219 Aeronautical mobile and robotic operation.

Entities eligible pursuant to § 90.1203(a) may conduct manned aeronautical mobile and robotic terrestrial operations on Channels 1 through 5 (4940–4945 MHz) to transmit video payload on a primary basis to terrestrial services under the following restrictions.

(a) Airborne use of these channels is limited to aircraft flying at or below 457 meters (1500 feet) above ground level. Fixed wing aircraft may use these channels at altitudes exceeding 457 meters above ground level as necessary to comply with 14 CFR 91.119(b) through (c).

(b) Licensees may use only low power devices as defined by § 90.1215 that use Emission Mask L as defined by § 90.210(l) for aeronautical mobile use.

(c) Licensees may use only low power devices as defined by § 90.1215 for robotic applications.

(d) The applicant shall provide a description of proposed operation to demonstrate that the proposed aeronautical mobile operations protect radio astronomy operations and terrestrial services from interference.

(e) Aeronautical mobile and robotic applications must be approved in writing by the 700 MHz Regional Planning Committee or the National Regional Planning Council as part of the frequency coordination Regional Planning Committee review process before the coordinator can submit the application to the Commission.

(f) Aeronautical mobile operations are prohibited within 80.5 kilometers (50 miles) of radio astronomy sites listed in § 2.106 US385 or US131. The coordinates to be used for the Allen Telescope Array are 40° 49' 01'' North latitude, 121° 28' 12'' West longitude. An applicant for aeronautical mobile use whose geographic boundaries fall within 80.5 kilometers of any of these radio astronomy sites may request a waiver, but shall certify that it has served a copy of the application on affected radio astronomy observatories.

(g) The Commission has the discretion to impose special conditions and operating restrictions on individual licenses as necessary to reduce risk of interference to radio astronomy operations and terrestrial services.

(h) Transmissions in the 4940–4990 MHz band to or from unmanned aerial systems are prohibited.

[FR Doc. 2018–09416 Filed 5–4–18; 8:45 am]

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Notices

Federal Register
Vol. 83, No. 88
Monday, May 7, 2018

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

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities; Comment Request: National Universal Product Code (NUPC) Database

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

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is an extension, without change, of a currently approved collection for the maintenance of a central repository containing information about authorized foods in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), as approved by various WIC State agencies.

DATES: Written comments must be received on or before July 6, 2018.

ADDRESSES: Comments may be sent to: Kurtria Watson, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 524, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Kurtria Watson at 703–305–2196 or via email to *Kurtria.Watson@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

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

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Kurtria Watson at 703–605–4387.

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

Title: National Universal Product Code (NUPC) Database.

Form Number: N/A.

OMB Number: 0584–0552.

Expiration Date: August 31, 2018.

Type of Request: Extension, without change, of a currently approved collection.

Abstract: The Special Supplemental Nutrition Program for Women, Infants and Children (WIC), (Pub. L. 109–85) provides low-income pregnant, breastfeeding, and postpartum women, infants, and children up to age five with nutritious supplemental foods, nutrition education, including breastfeeding promotion and support, and referrals to health and social services. The WIC Program is administered by the USDA Food and Nutrition Service (FNS). FNS provides grant funding and issues regulations which are utilized by WIC State agencies to operate the WIC Program and distribute benefits through local WIC clinics. The program operates throughout the 50 States, the District of Columbia, Guam, Puerto Rico, American Samoa, Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, and in 34 Indian Tribal Organizations.

The reporting and record-keeping associated with WIC State agencies and their management of the NUPC database is not included in this burden calculation. Burden hours associated with WIC State agencies and their management of the NUPC database is included in the burden calculation associated with the WIC program regulations, OMB Control Number 0584–0043.

WIC Regulations at 7 CFR part 246 require State agencies to authorize eligible foods for their WIC food list. Under these regulations, State agencies must review food products for eligibility in accordance with Federal regulations and State agency policies. State agencies are not required to authorize all food products eligible under federal regulations, but generally select foods based on factors such as cost, availability and acceptability to participants. After review, the State agency develops a list of food items available for WIC participants for purchase. This food list is known as the Authorized Products List (APL). State agencies require authorized vendors (*i.e.,* stores authorized to provide WIC foods) to ensure only approved food items are purchased. In State agencies that have transitioned to Electronic Benefit Transfer (EBT) systems, authorized vendors must program their point of sale systems to identify WIC approved foods and their associated Universal Product Code (UPC) or Price Look-Up (PLU) code as individual products are scanned at the checkout. Vendors in State agencies that have not transitioned to EBT rely on their checkout clerks to ensure only authorized WIC products are approved for purchase.

WIC State agencies operating EBT systems provide their authorized vendors with an electronic file containing the State agency's current list of authorized foods. As products are scanned at the checkout lane, the UPC or PLU is matched to the State specific APL. Food items matching the APL, and which are presented in quantities less than or equal to the remaining benefit balance associated with the participant's WIC EBT card, are approved for purchase. Unmatched items, or items in excess of the available account balance, may not be purchased with WIC benefits.

The Healthy, Hunger-Free Kids Act of 2010 directed the Secretary of Agriculture to establish a National Universal Product Code (NUPC) database for use by all WIC State agencies as they implement EBT statewide. As a result of this legislation, FNS expanded the number of data elements contained in the existing NUPC database while simultaneously

reducing the burden on WIC State agency employees by assembling food product information in an easily accessible repository. NUPC database modifications and expansion activities have allowed for the storage and retrieval of additional data elements for each WIC authorized food to include: Nutrition facts panel information, ingredients, special processing practices (*i.e.,* Kosher or Halal), and a free form comments field. The NUPC retained all previously used product identifier fields. Responsibility for populating the NUPC database resides with an independent contractor who serves as the single point of entry for all information entering the NUPC database. This contractor ensures NUPC data is captured with a high level of accuracy while preserving data integrity in a standardized format. The NUPC database provides all WIC State agencies with access to a central repository containing comprehensive information about authorized WIC foods. State agencies may choose to use the NUPC database to create an initial list of authorized foods eligible for redemption by WIC Program participants. Subsequently, State agencies may use the NUPC database to maintain their list of authorized foods, and to create an APL for distribution to authorized vendors when operating in the EBT environment.

Affected Public: Businesses or Other For Profit Organizations. Respondent groups identified include: (1) Food Manufacturers and Distributors; (2) Authorized Vendors.

Estimated Number of Respondents: The total estimated number of respondents is 360. This includes 240 food manufacturers or distributors and 120 authorized vendors.

Estimated Number of Responses per Respondent: 3.33. The 240 food manufacturers or distributors will be asked to provide product information in electronic format (.doc, .xls, .pdf). All responses are voluntary. FNS estimates that each of the food manufacturers or distributors will be asked to provide product information 4 times per year on average and that each of the 120 authorized vendors will be asked to provide product information 2 times per year on average.

Estimated Total Annual Responses: The total number of responses is estimated to be 1,200. FNS estimates food manufacturers or distributors will be asked to respond a total of 960 times per year (240 food manufacturers or distributors × 4 responses per year each = 960). FNS estimates authorized vendors will be asked to respond a total of 240 times per year (120 authorized vendors × 2 responses per year each = 240). All responses are voluntary.

Estimated Time per Response: The estimated time per response varies by type of respondent. FNS expects all respondents will expend 12 hours per respondent per year to develop, maintain, and troubleshoot the electronic systems for use in transmitting information. The estimated time required to develop, maintain, and troubleshoot electronic systems is amortized over the expected number of responses. FNS also expects all respondents will expend 2 seconds per response to transmit information to FNS electronically. Since the time required to actually transmit the information to FNS is considered negligible (total of 40 minutes per year for all respondents), it was omitted from the burden calculation. FNS expects that food manufacturers or distributors will expend 6 hours per response to gather and format the requested information. Authorized vendors are expected to expend 1 hour per response to gather and format the requested information. The estimated time per response for food manufacturers or distributors is expected to be 9 hours per response ((12 hours per year/4 responses per year) + 6 hours per response = 9 hours per response). The estimated time per response for authorized vendors is expected to be 7 hours per response ((12 hours per year/2 responses per year) + 1 hour per response = 7 hours per response).

Estimated Total Annual Burden on Respondents: 10,320 hours. The table below provides an estimated total annual burden for each type of respondent:

Respondent	Estimated number of respondents	Response annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total annual burden (hours)
Food Manufacturers and Distributors	240	4	960	9	8,640
Authorized Vendors	120	2	240	7	1,680
Total	360	3.33	1,200	8.6	10,320

Dated: April 27, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2018–09625 Filed 5–4–18; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–28–2018]

Foreign-Trade Zone (FTZ) 37—Orange County, New York; Notification of Proposed Production Activity; Takasago International Corp. (U.S.A.) (Fragrances); Harriman, New York

Takasago International Corp. (U.S.A.) (Takasago) submitted a notification of proposed production activity to the FTZ Board for its facility in Harriman, New York. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on April 30, 2018.

Takasago already has authority to produce fragrances within Site 10 of FTZ 37. The current request would add additional foreign status components of essential oils and aromatic chemicals to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status components described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Takasago from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status components noted below,

Takasago would be able to choose the duty rate during customs entry procedures that applies to fragrances (duty-free). Takasago would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include: Decanoyl and Octanoyl Glycerides; Beeswax Absolute; Cinnamyl Isovalerate; Camphene; Farnesene; Galbanolene Super (Ethyl Citrate); Ocimene; Dimethyl Benzyl Carbinol; Lily Propanol; Phenyl Ethyl Methyl Ethyl Carbinol; Grapefruit Pentanol; Styrallyl Alcohol; Isobutyl Benzyl Carbinol; Diola; Woody Epoxide; Ocimene Oxirane; Rhubarb Oxirane; Caryophyllene Oxide; Citral Dimethyl Acetal Extra; Elintaal Forte; Floropal; Hyacinth Body; Hydratropic Aldehyde; Hydratropic Aldehyde Dimetheyl Acetal; Indoletal; Karanal; Methyl Pamplemousse; Octacetal; Phenyl Acetald Glyceryl Acetal; Syvertal; Phenyl Ethyl Acetal; Alpha-Amyl Cinnamic Aldehyde; 2(1)-Orris Butanal; Cinnamic Aldehyde; Cyclovertal; Muguet Carbaldehyde; Dupical; Floralozone; Hexyl Cinnamic Aldehyde; Hydroxyambran; Iso Cyclo Citral; Alpha-Methyl Cinnamic Aldehyde; Mefranal; Perilla Aldehyde; Para-Tolyl Aldehyde; Ligustral; Vernaldehyde; Hinokitiol Crystal; Methyl Lavender Ketone; Citronellyl Isovalerate; Para-Cresyl Isobutyrate; Dimethyl Benzyl Carbinyl Butyrate; Geranyl Butyrate; Isoamyl Butyrate; Isoamyl Isobutyrate; Isobutyl Lignate; Linalyl Butyrate; Methyl Isovalerate; Phenyl Ethyl Pivalate; Methyl Cinnamate; Phenyl Ethyl Cinnamate; Benzyl Cinnamate; Diethyl Tartrate; Methyl Jasmonate; Ethyl 3-Hydroxy Butyrate; Ethyl Levulinate; Ethyl Decadienoate; Methyl Dihydrojasmonate; Allyl Amyl Glycolate; Berry Hexanoate; Aurantiol Pure; Agrumea; Lyrame; Methional; Corps Pamplemousse; Dibutyl Sulfide; Dimethyl Sulfide; 2-Methyl-4-Propyl-1 3-Oxathiane; Ambrettolide; Gamma-Decalactone; Jasmolactone; Delta-Octalactone; Cyclohexyl Lactone; Delta-Decalactone; Gamma-Decalactone; Cyclopentadecanolide; Gamma-Heptalactone; Gamma-Hexalactone; Jasmin Lactone; Lactone of CIS Jasmone; Lactone of Dihydro Jasmone; Musk R-1; Delta-Nonalactone; Delta-Undecalactone; Gamma-Undecalactone; Gamma-Valerolactone; Whiskey Lactone (Methyl Octalactone); Gamma-Nonalactone; Methyl Nonyl Acetaldehyde; Watermelon Ketone; Dulcinyl; Galaxolide Pure; Galaxolide 50% Dipropylene Glycol; Methyl Dioxolan; Woody Dioxolane; Spirambrene; Floropal; Glycolierral; Grisalva; Gyrane; Ocean Propanal; Floral Pyranol; Maltol Isobutyrate; Magnolan; 10-Oxahexadecanolide; Pelargene; Rose Oxide; Reseda Body; Laevo Rose Oxide; Isobutyl Quinoline; Isopropyl Quinoline; 2-Isobutyl Quinoline; Marine Pyridine; Mandarin Oil Cravo Brazil; Orange Juice Carbonyls Low Valencene; Orange Oil Terpenes; Neroli Oil; Orange Isolate; Linalool; Orange Flower Absolute Carbon Dioxide; Orange Sweet Oil; Orange Leaf Water Tunisia Absolute Natural; Tangerine Oil; Orange Bigarade (Bitter) Molecular Distilled; Peppermint Oil Chinese Natural; Benzoin Resin Siam Natural; Benzoin Resin Sumatra Super Natural; Elemi Gum; Ginger Oil Indian; Hydrocarboresin; Myrrh Resin; Myrrh Resin Coeur; Oakmoss Absolute; Opoponax Oil; Styrax Oil; Tolu Balsam (Benzoic Acid); Nutmeg Oil; Ambroxide; Iris Pallida; and, Opoponax Resin Natural Extract (duty rate ranges from duty-free to 6.5%, as well as 8.8 ¢/kg).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 18, 2018.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita Chen at *juanita.chen@trade.gov* at 202–482–1378.

Dated: May 2, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–09635 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–66–2018]

Foreign-Trade Zone 29—Louisville, Kentucky; Application for Subzone; Amcor Flexibles LLC; Shelbyville, Kentucky

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Louisville & Jefferson County Riverport Authority, grantee of FTZ 29, requesting subzone status for the facility of Amcor Flexibles LLC, located in Shelbyville, Kentucky. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on May 1, 2018.

The proposed subzone site (14.364 acres) is located at 6850 Midland Industrial Drive, Shelbyville, Shelby County. Limited production activity was authorized for the company within FTZ 29 on May 11, 2017 (Doc. B–7–2017). The proposed subzone would be subject to the existing activation limit of FTZ 29.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 18, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to July 2, 2018.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: May 1, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–09634 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Subsidy Programs Provided by Countries Exporting Softwood Lumber and Softwood Lumber Products to the United States; Request for Comment

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

SUMMARY: The Department of Commerce (Commerce) seeks public comment on any subsidies, including stumpage subsidies, provided by certain countries exporting softwood lumber or softwood lumber products to the United States during the period July 1, 2017, through December 31, 2017.

DATES: Comments must be submitted within 30 days after publication of this notice.

ADDRESSES: *See* the Submission of Comments section below.

FOR FURTHER INFORMATION CONTACT: James Terpstra or Brendan Quinn, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3965 or (202) 482–5848, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 18, 2008, section 805 of Title VIII of the Tariff Act of 1930 (the Softwood Lumber Act of 2008) was enacted into law. Under this provision, the Secretary of Commerce is mandated to submit to the appropriate Congressional committees a report every 180 days on any subsidy provided by countries exporting softwood lumber or softwood lumber products to the United States, including stumpage subsidies.

Commerce submitted its last subsidy report on December 16, 2017. As part of its newest report, Commerce intends to include a list of subsidy programs identified with sufficient clarity by the public in response to this notice.

Request for Comments

Given the large number of countries that export softwood lumber and softwood lumber products to the United States, we are soliciting public comment only on subsidies provided by countries the exports of which accounted for at least one percent of total U.S. imports of softwood lumber by quantity, as classified under Harmonized Tariff Schedule code 4407.1001 (which accounts for the vast majority of imports), during the period July 1, 2017, through December 31, 2017. Official U.S. import data published by the United States International Trade Commission Tariff and Trade DataWeb indicate that four countries (Brazil, Canada, Germany and Sweden) exported softwood lumber to the United States during that time period in amounts sufficient to account for at least one percent of U.S. imports of softwood lumber products. We intend to rely on similar previous six-month periods to identify the countries subject to future reports on softwood lumber subsidies. For example, we will rely on U.S. imports of softwood lumber and softwood lumber products during the period January 1, 2018 through June 30, 2018, to select the countries subject to the next report.

Under U.S. trade law, a subsidy exists where an authority: (i) Provides a financial contribution; (ii) provides any form of income or price support within the meaning of Article XVI of the GATT 1994; or (iii) makes a payment to a funding mechanism to provide a financial contribution to a person, or entrusts or directs a private entity to make a financial contribution, if providing the contribution would normally be vested in the government and the practice does not differ in substance from practices normally followed by governments, and a benefit is thereby conferred.[1]

Parties should include in their comments: (1) The country which provided the subsidy; (2) the name of the subsidy program; (3) a brief description (no more than 3–4 sentences) of the subsidy program; and (4) the government body or authority that provided the subsidy.

Submission of Comments

As specified above, to be assured of consideration, comments must be received no later than 30 days after the publication of this notice in the **Federal Register**. All comments must be submitted through the Federal eRulemaking Portal at *http://www.regulations.gov,* Docket No. ITA–2018–0002, unless the commenter does not have access to the internet. The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only.

Commenters who do not have access to the internet may submit the original and one electronic copy of each set of comments by mail or hand delivery/courier.

All comments should be addressed to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, Room 18022, Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230.

Dated: May 1, 2018.

Gary Taverman,

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

[FR Doc. 2018–09631 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See* section 771(5)(B) of the Tariff Act of 1930, as amended.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–879]

Polytetrafluoroethylene Resin From India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that polytetrafluoroethylene (PTFE) resin from India is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2016, through June 30, 2017. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Nicholas Czajkowski or Mark Kennedy, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1395 or (202) 482–7883, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on October 26, 2017.[1]

Commerce exercised its discretion to toll all deadlines affected by the closure of the Federal Government from January 20 through 22, 2018.[2] Accordingly, the

[1] *See Polytetrafluoroethylene Resin from India and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 49587 (October 26, 2017) (*Initiation Notice*).

[2] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated

Continued

revised deadline for the preliminary determination of this investigation became March 12, 2018.[3] Subsequently, on February 20, 2018, Commerce postponed the preliminary determination of this investigation and the revised deadline is now April 30, 2018.[4] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[5] A list of topics addressed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The product covered by this investigation is PTFE resin from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[6] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (scope).[7] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[8] *See* the scope in Appendix I to this notice. The scope case briefs were due on April 9, 2018, 30 days after the publication of *PTFE Resin from India CVD.*[9] There will be no further opportunity for comments on scope-related issues.[10]

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually examined, excluding all rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In this investigation, Commerce has preliminarily determined a calculated rate for Gujarat Fluorochemicals Limited, the one mandatory respondent in this investigation, that is not zero, *de minimis,* or based entirely on facts otherwise available. Consequently, the rate calculated for this respondent is also assigned as the rate for all-other producers and exporters in this investigation.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent *ad valorem*)	Cash deposit rate (adjusted for export subsidy offset) (percent *ad valorem*)
Gujarat Fluorochemicals Limited	18.49	[11] 17.16
All-Others	18.49	[12] 17.16

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping

January 23, 2018. All deadlines in this segment of the proceeding have been extended by 3 days.

[3] *Id.*

[4] *See Polytetrafluoroethylene Resin from India: Postponement of Preliminary Determination of Antidumping Duty Investigation,* 83 FR 8423 (February 27, 2018).

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Polytetrafluoroethylene Resin from India'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[7] *See Initiation Notice.*

[8] *See* Memorandum, ''Polytetrafluoroethylene Resin from India and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated February 28, 2018 (Preliminary Scope Decision Memorandum).

[9] The scope case briefs were due 30 days after the publication of *Polytetrafluoroethylene Resin from India: Preliminary Affirmative Countervailing Duty Determination,* 83 FR 9842 (March 8, 2018) (*PTFE Resin from India CVD*), which was Saturday, April 7, 2018. *See* the Preliminary Scope Decision Memorandum at 2. Therefore, the actual deadline for the scope case briefs was Monday, April 9, 2018. *See* 19 CFR 351.303(b)(1) (''For both electronically filed and manually filed documents, if the applicable due date falls on a non-business day, the Secretary will accept documents that are filed on the next business day.''). The deadline for scope rebuttal briefs was Monday, April 16, 2018.

[10] *See* Preliminary Scope Decision Memorandum at 3 (''Parties should include all arguments about scope-related issues in the scope case and scope rebuttal briefs. Commerce does not intend to permit arguments about scope-related issues in the investigation-specific case and rebuttal briefs regarding other issues.'')

[11] *See Polytetrafluoroethylene Resin from India: Preliminary Affirmative Countervailing Duty Determination,* 83 FR 9842 (March 8, 2018) and accompanying Preliminary Decision Memorandum at ''Programs Preliminarily Determined to Be Countervailable'' (specifically, Export Promotion of Capital Goods Scheme (EPCGS); Advance Authorization Program (AAP) aka Advance License Program (ALP); and Status Holders Incentive Scrip (SHIS)).

[12] *Id.*

margin or the estimated all-others rate, adjusted for export subsidies, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination, adjusted for export subsidies; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise, adjusted for export subsidies; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin, adjusted for export subsidies.

For cash deposits, Commerce normally adjusts the estimated weighted-average dumping margins by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce has preliminarily made an affirmative determination that there are countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate attributable to export subsidies. Any such cash deposit rate may be found in the Preliminary Determination section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for the countervailable export subsidies at the time that the provisional CVD measures expire.[13]

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation.[14] Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[15] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On March 28, 2018, pursuant to 19 CFR 351.210(e), GFL requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[16] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce's final determination will be published no later than 135 days after the date of publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: April 30, 2018.

Gary Taverman,

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

Appendix I—Scope of the Investigation

The product covered by this investigation is polytetrafluoroethylene (PTFE) resin, including but not limited to granular, dispersion, or coagulated dispersion (also

[13] *See Polytetrafluoroethylene Resin from India: Preliminary Affirmative Countervailing Duty Determination,* 83 FR 9842 (March 8, 2018).

[14] Case briefs, other written comments, and rebuttal briefs should not include scope-related issues. *See* Preliminary Scope Decision Memorandum at 2–3. Parties were already permitted the opportunity to file scope case briefs. *Id.*

[15] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[16] *See* Letter from GFL, ''Polytetrafluoroethylene (PTFE) Resin from India: Gujarat Fluorochemicals Ltd.'s Request to Postpone Final Determination,'' dated March 28, 2018.

known as fine powder). PTFE is covered by the scope of this investigation whether filled or unfilled, whether or not modified, and whether or not containing co-polymer additives, pigments, or other materials. Also included is PTFE wet raw polymer. The chemical formula for PTFE is C2F4, and the Chemical Abstracts Service Registry number is 9002–84–0.

PTFE further processed into micropowder, having particle size typically ranging from 1 to 25 microns, and a melt-flow rate no less than 0.1 gram/10 minutes, is excluded from the scope of this investigation.

PTFE is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3904.61.0010 and 3904.61.0090. Subject merchandise may also be classified under HTSUS subheading 3904.69.5000. Although the HTSUS subheadings and CAS Number are provided for convenience and Customs purposes, the written description of the scope is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–09633 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the United States Travel and Tourism Advisory Board

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

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Thursday, May 24, 2018. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to discuss recommendations related to the importance of international travel and tourism to the United States. The final agenda will be posted on the Department of Commerce website for the Board at *http://trade.gov/ttab* at least one week in advance of the meeting.

DATES: Thursday, May 24, 2018, 3:00 p.m.–4:30 p.m. EDT. The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EDT on Thursday, May 17, 2018.

ADDRESSES: The meeting will be held in Washington, DC. The exact location will be provided by email to registrants.

Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 10003, Washington, DC 20230 or by email to *TTAB@trade.gov.* Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Brian Beall, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 10003, Washington, DC 20230; telephone: 202–482–0140; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on Thursday, May 17, 2018, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Brian Beall at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on Thursday, May 17, 2018, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

Brian Beall,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2018–09642 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–812]

Steel Wire Garment Hangers From the Socialist Republic of Vietnam: Rescission of Antidumping Duty Administrative Review; 2017–2018

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

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty (AD) order on steel wire garment hangers from the Socialist Republic of Vietnam (Vietnam) for the period of review (POR) February 1, 2017, through January 31, 2018.

DATES: Applicable May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Trenton Duncan or Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3539 or (202) 482–2593, respectively.

Background

On February 1, 2018, Commerce published in the **Federal Register** a

notice of opportunity to request an administrative review of the AD order on steel wire garment hangers from Vietnam for the period February 1, 2017, through January 31, 2018.[1] On February 28, 2018, M&B Metal Products Company, Inc. (the petitioner), timely requested a review of the AD order with respect to 66 companies.[2] On April 16, 2018, Commerce initiated an administrative review with respect to these companies, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.221(c)(1)(i).[3] On April 24, 2018, the petitioner timely withdrew its request for an administrative review of all 66 companies listed in the *Initiation Notice*.[4] No other party requested a review of these exporters or any other exporters of subject merchandise.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review. In this case, the petitioner timely withdrew its requests for review within the 90-day deadline. Because Commerce received no other requests for review of the above-referenced companies, and no other requests were made for a review of the AD order on steel wire garment hangers from Vietnam with respect to other companies, we are rescinding the administrative review covering the period February 1, 2017, through January 31, 2018, in its entirety, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of steel wire garment hangers from Vietnam during the POR at rates equal to the cash deposit rate for estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

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

Notification Regarding Administrative Protective Order

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

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: May 1, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–09630 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 4639 (February 1, 2018).

[2] *See* Petitioner's Letter, ''Steel Wire Garment Hangers from Vietnam: Request for Fifth Administrative Review,'' dated February 28, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 16298 (April 16, 2018) (*Initiation Notice*).

[4] *See* Petitioner's Letter, ''Fifth Administrative Review of Steel Wire Garment Hangers from Vietnam—Petitioner's Withdrawal of Review Request,'' dated April 24, 2018.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–066]

Polytetrafluoroethylene Resin From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that polytetrafluoroethylene (PTFE) resin from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2017, through June 30, 2017. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Michael Romani, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0410 or (202) 482–0198, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on October 26, 2017.[1]

Commerce exercised its discretion to toll all deadlines affected by the closure of the Federal Government from January 20 through 22, 2018.[2] Accordingly, the revised deadline for the preliminary determination of this investigation became March 12, 2018.[3] Subsequently, on February 20, 2018, Commerce postponed the preliminary determination of this investigation and the revised deadline is now April 30, 2018.[4] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[5] A list of topics addressed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's

[1] *See Polytetrafluoroethylene Resin from India and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 49587 (October 26, 2017) (*Initiation Notice*).

[2] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated January 23, 2018. All deadlines in this segment of the proceeding have been extended by 3 days.

[3] *Id.*

[4] *See Polytetrafluoroethylene Resin from the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation,* 83 FR 8423 (February 27, 2018).

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Polytetrafluoroethylene Resin from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Scope of the Investigation

The product covered by this investigation is PTFE resin from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[6] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (scope).[7] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this investigation, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[8] *See* the scope in Appendix I to this notice. The scope case briefs were due on April 9, 2018, 30 days after the publication of *PTFE Resin from India CVD.*[9] There will be no further opportunity for comments on scope-related issues.[10]

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Export prices were calculated in accordance with section 772(a) of the Act; constructed export prices were calculated in accordance with section 772(b) of the Act. Because China is a non-market economy, within the meaning of section 771(18) of the Act, Commerce calculated normal value (NV) in accordance with section 773(c) of the Act. In addition, pursuant to section 776(a) and (b) of the Act, Commerce preliminarily relied on facts otherwise available, with adverse inferences, for the China-wide entity. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[11] we stated that we would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[12] In this investigation, we calculated producer/exporter combination rates for respondents eligible for separate rates.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent *ad valorem*)
Daikin Fluorochemicals (China) Co., Ltd	Daikin Fluorochemicals (China) Co., Ltd	84.75
Shandong Dongyue Polymer Material Co., Ltd	Shandong Dongyue Polymer Material Co., Ltd	69.34
Hangzhou Fine Fluorotech Co., Ltd	Qingdao Orientalflon New Materials Co., Ltd	78.74
Hangzhou Fine Fluorotech Co., Ltd	Zhejiang Juhua Co., Ltd. Fluor-Polymeric Plant	78.74
Shanghai Huayi 3f New Materials Sales Co., Ltd	Shanghai 3f New Materials Co., Ltd	78.74
China-Wide Entity		208.16

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in Appendix I entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which NV exceeds U.S. price, as indicated in the chart above as follows: (1) For the exporter/producer combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of China producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the China exporter/producer combination (or the China-wide entity) that supplied that third-country exporter.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this

[6] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[7] *See Initiation Notice.*

[8] *See* Memorandum, ''Polytetrafluoroethylene Resin from India and the People's Republic of China: Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated February 28, 2018 (Preliminary Scope Decision Memorandum).

[9] The scope case briefs were due 30 days after the publication of *Polytetrafluoroethylene Resin from India: Preliminary Affirmative Countervailing Duty Determination,* 83 FR 9842 (March 8, 2018) (*PTFE Resin from India CVD*), which was Saturday, April 7, 2018. *See* the Preliminary Scope Decision Memorandum at 2. Therefore, the actual deadline for the scope case briefs was Monday, April 9, 2018. *See* 19 CFR 351.303(b)(1) (''For both electronically filed and manually filed documents, if the applicable due date falls on a non-business day, the Secretary will accept documents that are filed on the next business day.''). The deadline for scope rebuttal briefs was Monday, April 16, 2018.

[10] *See* Preliminary Scope Decision Memorandum at 3 (''Parties should include all arguments about scope-related issues in the scope case and scope rebuttal briefs. Commerce does not intend to permit arguments about scope-related issues in the investigation-specific case and rebuttal briefs regarding other issues.'')

[11] *See Initiation Notice* at 49591.

[12] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation.[13] Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[14] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

In March 2018, pursuant to 19 CFR 351.210(e), Shandong Dongyue Polymer Material Co., Ltd., and Daikin Fluorochemicals (China) Co., Ltd., requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[15] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce's final determination will be published no later than 135 days after the date of publication of this preliminary determination.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: April 30, 2018.

Gary Taverman,

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

Appendix I

Scope of the Investigation

The product covered by this investigation is polytetrafluoroethylene (PTFE) resin, including but not limited to granular, dispersion, or coagulated dispersion (also known as fine powder). PTFE is covered by the scope of this investigation whether filled or unfilled, whether or not modified, and whether or not containing co-polymer additives, pigments, or other materials. Also included is PTFE wet raw polymer. The chemical formula for PTFE is C2F4, and the Chemical Abstracts Service Registry number is 9002–84–0.

PTFE further processed into micropowder, having particle size typically ranging from 1 to 25 microns, and a melt-flow rate no less than 0.1 gram/10 minutes, is excluded from the scope of this investigation.

PTFE is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3904.61.0010 and 3904.61.0090. Subject merchandise may also be classified under HTSUS subheading 3904.69.5000. Although the HTSUS subheadings and CAS Number are provided for convenience and Customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–09632 Filed 5–4–18; 8:45 am]

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[13] Case briefs, other written comments, and rebuttal briefs should not include scope-related issues. *See* Preliminary Scope Decision Memorandum at 2–3. Parties were already permitted the opportunity to file scope case briefs. *Id.*

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

[15] *See* Letter from Shandong Dongyue Polymer Material Co., Ltd., ''PTFE Resin from the People's Republic of China: Request to Postpone the Final Results of the Investigation,'' dated March 19, 2018, and Letter from Daikin Fluorochemicals (China) Co., Ltd., ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China: Request to Postpone Final Determination,'' dated March 20, 2018.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG128

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice of Availability of a draft environmental assessment; request for comments.

SUMMARY: Notice is hereby given that NMFS has prepared a draft environmental assessment (EA) under the National Environmental Policy Act (NEPA) describing the potential effects of the continued operation of one hatchery program in the San Joaquin River Basin of California. The Hatchery and Genetic Management Plan (HGMP) for the program was prepared and submitted by the United States Fish and Wildlife Service (USFWS) and the California Department of Fish and Wildlife (CDFW). All comments and other information received will become part of the public record and will be available for review.

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on June 6, 2018.

ADDRESSES: Written comments on the draft EA should be addressed to the NMFS California Central Valley Office, Attn: San Joaquin Hatchery EA, 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814. Comments may also be submitted via fax to 916–930–3629 or by email to *SanJoaquinHatcheryEA.wcr@noaa.gov.* Include in the subject line of the email comment the following identifier: Comments on San Joaquin Hatchery EA. When commenting on the draft EA, please refer to the specific page number and line number of the subject of your comment. The documents are available on the internet at *www.westcoast.fisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Amanda Cranford, Sacramento, CA, at phone number: (916) 930–3706, via fax: (916) 930–3629, or via email: *Amanda.Cranford@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): threatened, naturally produced and artificially propagated Central Valley spring-run (CVSR).

Steelhead (*O. mykiss*): threatened, naturally produced and artificially propagated California Central Valley (CCV).

Background

The USFWS and CDFW, under the auspices of the San Joaquin River Restoration Program (SJRRP), are working to restore a CVSR Chinook salmon population in the San Joaquin River. The reintroduced CVSR Chinook salmon, taken from one or more out-of-basin stocks, are designated as a non-essential, experimental population under section 10(j) of the Endangered Species Act (ESA), and have associated 4(d) take provisions (78 FR 79622). The SJRRP determined that a conservation hatchery would be the preferred and primary strategy for reintroducing CVSR Chinook salmon to the San Joaquin River. The San Joaquin River Salmon Conservation and Research Program (Conservation Program) involves the operation of two facilities: the Salmon Conservation and Research Facility (SCARF) currently under construction, with completion expected summer of 2018, and an interim SCARF (Interim Facility) currently in operation. The Conservation Program is operated as an Integrated-Recovery hatchery program, intended to help meet fisheries management objectives while achieving restoration and recovery goals.

This CVSR Chinook salmon HGMP submitted by the USFWS and CDFW, pursuant to section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR part 222), provides guidance on the management and operation of the SCARF and Interim Facility in the San Joaquin River Basin. The HGMP and the associated section 10(a)(1)(A) enhancement permit application (20571) were made available for public review and comment on July 27, 2017 (82 FR 34931). On August 8, 2017, NMFS determined that the submitted HGMP was sufficient for consideration under section 10(a)(1)(A) of the ESA. The draft environmental assessment available for comment evaluates the potential effects of approving the CVSR Chinook salmon HGMP and issuing an ESA section 10(a)(1)(A) Permit 20571 to the USFWS and CDFW.

Authority

NEPA requires Federal agencies to conduct an environmental analysis of their proposed actions to determine if the actions may affect the human environment. Therefore, NMFS is seeking public input on the scope of the required NEPA analysis, including the range of reasonable alternatives and associated impacts of any alternatives.

Dated: May 1, 2018.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–09570 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF100

National Process for Permit Applications To Retain Releasable Rehabilitated Marine Mammals for Public Display

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

ACTION: Notice; response to comments.

SUMMARY: The National Marine Fisheries Service (NMFS) announces the availability of its final Procedural Directive clarifying the process for eligible permit applicants to obtain releasable marine mammals for public display purposes under the Marine Mammal Protection Act (MMPA). NMFS will no longer grant permits for the specific purpose of retaining releasable marine mammals for public display. Instead, applicants will now need to apply for a permit to take (collect) animals from the wild pursuant to the MMPA.

DATES: This final Procedural Directive will be applicable as of May 7, 2018.

ADDRESSES: The Procedural Directive is available in electronic form via the internet at *https://www.fisheries.noaa.gov/national/laws-and-policies/protected-resources-policy-directives.*

FOR FURTHER INFORMATION CONTACT: Jaclyn Taylor, NMFS, Office of Protected Resources, (301) 427–8402, *Jaclyn.Taylor@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS developed a national Procedural Directive clarifying the process for eligible permit applicants to obtain releasable marine mammals for public display purposes under the MMPA.

NMFS will no longer accept applications for MMPA section 104 permits that specifically seek to obtain releasable rehabilitated marine mammals for public display purposes. NMFS will instead require prospective

applicants to apply for a permit authorizing actual take (collect) from the wild. In the event NMFS grants a permit for take from the wild, the NMFS OPR Director may then, at his or her discretion, require that a releasable rehabilitated marine mammal be substituted for the authorized capture from the wild, in accordance with 50 CFR 216.27.

On November 15, 2017, NMFS published the draft national Procedure for Permit Applications to Retain Releasable Rehabilitated Marine Mammals for Public Display for a 30-day public comment period (82 FR 52880). Comments received are available on regulations.gov at *https://www.regulations.gov/docket?D=NOAA-NMFS-2017-0096.* Substantive and relevant comments and NMFS' responses are included below.

General Comments

Comment 1: Several commenters expressed support for the draft Procedural Directive, stating that it provides clarity and reflects concerns offered during public comment periods in 2010 and 2015 regarding the Office of Protected Resource's issuance of permits authorizing the acquisition of stranded, releasable California sea lions (*Zalophus californianus*) from the National Marine Mammal Health and Stranding Response Program for the purposes of public display. The commenters opined that the directive aligns more clearly with the stated goals of the Marine Mammal Health and Stranding Response Program by requiring the application for a permit to ''take'' marine mammals from the wild, leaving potential sourcing of releasable marine mammals from rehabilitation facilities, appropriately, to the discretion of the Director of the Office of Protected Resources.

Response: NMFS acknowledges this comment and has finalized the Procedural Directive as proposed.

Comment 2: One commenter recommended NMFS provide additional explanation and rationale for finding that either its existing practice or the procedural directive is consistent with MMPA section 109(h)(3).

Response: NMFS's rationale for both the existing practice and this Procedural Directive is described in the Additional Background and Rationale section in the Directive. The rationale outlines each of the following, which contribute to the rationale: the preamble to the 1993 proposed rule (58 FR 53320) for 50 CFR 216.27, the implementing regulations allowing the Office Director broad discretion to direct a releasable animal to be used for a MMPA section 104 purpose in lieu of being released, and the three relevant permit decisions.

Comment 3: One commenter stated that it is incumbent on NOAA to provide a certification that a rehabilitated animal will not carry back into the wild any communicable disease. Additionally, NOAA should ensure the released marine mammal will become part of the stock or group that it originally came from.

Response: The Standards for Release, as described in this Directive, provide an evaluative process to determine if a stranded marine mammal is suitable for release back to the wild in accordance with MMPA implementing regulations at 50 CFR 216.27. As part of this process the attending veterinarian reviews the animal's complete history including all stranding information, diagnostic test results required by NMFS, and medical and husbandry records. The goal of required diagnostic testing is to safeguard the health of wild marine mammal populations by testing for diseases that pose a significant morbidity or mortality risk to wild populations. With regards to the released animal becoming part of the stock or group that it originally came from, the Standards for Release specify that rehabilitated animals should be released in a location and at a time of year to maintain stock fidelity and ensure proximity to conspecifics.

Comment 4: One commenter objected to the draft Directive, suggesting NMFS instead propose a new process that is compatible with the principles of the MMPA and is reasonably targeted to and appropriate for rehabilitated marine mammals deemed releasable.

Response: NMFS believes that this Procedural Directive is compatible with the principles of the MMPA. The purpose of this Procedural Directive is to explain that NMFS will no longer accept applications that specifically seek to obtain releasable rehabilitated marine mammals, which, as described in the Directive, is consistent with the goals of both the MMPA's stranding response mandate and the public display permit provisions.

Procedural Directive Scope

Comment 5: One commenter recommended that NMFS clarify how it is defining the term ''feasible'' in the context of section 109(h)(3) of the MMPA—*e.g.,* does it mean that release can be accomplished, or that release is reasonable or sensible given the entirety of the facts of the particular situation? Specifically, NMFS should explain the basis for concluding that the issuance of a permit under section 104(c) somehow overrides the release mandate under section 109(h).

Response: The MMPA implementing regulations at 50 CFR 216.27 allow the Office Director broad discretion to direct that a rehabilitated animal to be used for a MMPA section 104 purpose in lieu of being released. As described in the Directive, the preamble to the 1993 proposed rule addressed the ''feasibility'' determination. Contrary to the commenter's suggestion, NMFS has not concluded in this Directive that issuance of a permit under section 104 ''overrides'' the release mandate under section 109(h). In fact, this directive is intended to separate ''takes'' for public display purposes (which are permitted under section 104) from the rehabilitation-and-release objectives of section 109(h), while still retaining the Office Director's discretion, as provided by the regulations, to direct a substitution in certain circumstances not enumerated in this directive.

As for the commenter's other questions regarding the releasability determination, as noted above, NMFS has established an evaluative process (the Standards for Release) to determine if a marine mammal is suitable for release back to the wild.

Comment 6: One commenter expressed support for NMFS's proposal to strengthen its analysis of population effects of retaining a releasable marine mammal as part of its permit application review. The commenter questioned whether similar scrutiny needs to be given to all aspects of a permit authorizing the removal of a marine mammal from the wild, if what the applicant is seeking or what NMFS plans to grant is authority to retain a releasable animal and not to remove animals from the wild population. The commenter recommended that NMFS clarify whether all of the information identified in the application instructions must be provided if the applicant is seeking a removal permit only as a means to obtain releasable rehabilitated animals and whether all of those details will be reflected in the requirements of the permit.

Response: The purpose of this Procedural Directive is to explain that NMFS will no longer accept applications that specifically seek to obtain releasable rehabilitated marine mammals. Applicants will be instructed to submit ''take from the wild'' permit applications with all required information for that take activity included in the permit application. If such permit is issued, the Office Director, in his or her sole discretion, will be responsible for the decision as to whether a releasable rehabilitated

animal be substituted for a take from the wild, depending on the circumstances before the Office Director at the time. This Procedural Directive is not intended to prescribe the situations, if any, in which the Office Director would in fact choose to exercise that discretion.

Comment 7: One commenter recommended that NMFS provide additional guidance on what releasable marine mammals can be used in place of animals authorized to be removed from the wild under the associated public display permit.

Response: As noted above and in the Procedural Directive itself, the purpose of this Directive is to explain that NMFS will no longer accept permit applications seeking to obtain releasable marine mammals from the stranding network. The Directive is not intended to prescribe criteria for what situations, if any, the Office Director would in fact exercise their discretion to direct a releasable rehabilitated animal be used for a MMPA section 104 purpose in lieu of being released.

Comment 8: One commenter recommended that the procedural directive be expanded to address the roles, rights, and responsibilities of rehabilitation facilities in implementing this policy. The district court in *IMMS* v. *NMFS, No. 1:11CV318–LG–JMR* (S.D.Miss.2014) found that NMFS could not delegate its authority to the rehabilitation facility to determine when releasable marine mammals are sent to a public display facility under NMFS' regulations. However, the court did not go so far as to say that the rehabilitation facility has no role in this process, provided that NMFS retains the ultimate decision-making authority.

Response: As noted above, the purpose of this Procedural Directive is to explain NMFS will no longer accept permit applications seeking to obtain releasable marine mammals from the stranding network. The Directive is not intended to prescribe criteria for what situations, if any, the Office Director would in fact exercise their discretion to direct a releasable rehabilitated animal be used for a MMPA section 104 purpose in lieu of being released.

Comment 9: One commenter stated that allowing a public display facility to substitute a stranded releasable marine mammal instead of ''taking'' from the wild is consistent with the requirements of the MMPA and should not be left to the discretion of the Agency.

Response: As noted above, NMFS' regulations at 50 CFR 216.27 allow the Office Director (as opposed to permittees or rehabilitation facilities) broad discretion to direct that a rehabilitated animal to be used for a MMPA section 104 purpose in lieu of being released.

Comment 10: One commenter expressed concern that the Proposed Directive would make it nearly impossible for a public display facility to obtain a releasable marine mammal under any circumstances because it would expose both the agency and the facility to the very likely risk of costly litigation initiated by those who oppose any animals in human care.

Response: The MMPA section 104 allows for permits to be issued for ''take'' of marine mammals for public display purposes provided that the applicant meets the issuance criteria as outlined in NMFS implementing regulations (50 CFR part 216, subpart D). As noted above, NMFS' regulations at 50 CFR 216.27 allow the Office Director broad discretion to direct that a rehabilitated animal to be used for a MMPA section 104 purpose (*e.g.,* a permitted use) in lieu of being released.

MMPA Permit Application Process

Comment 11: Several commenters expressed concern that the process set forth in the Directive (requiring prospective applicants to submit ''take from the wild'' permit applications) would be burdensome because it would require preparation of an Environmental Assessment and/or an Environmental Impact Statement under the National Environmental Policy Act (NEPA).

Response: All MMPA permits require appropriate analysis under NEPA. Environmental Assessments were prepared for the three permits NOAA issued authorizing the retention of releasable marine mammals.

Comment 12: A commenter expressed concern that requiring a zoo, aquarium or marine park that is only interested in retaining a releasable marine mammal to respond to a multitude of capture from the wild questions that fail to assess the suitability of the specific request to retain a releasable marine mammal would impose a regulatory burden that is unreasonable and unrelated to the best interests of the animal or the environment. The commenter also commented that requirements, as described in the Application Instructions and Supplemental Information for Public Display Permits under the MMPA (OMB No. 0648–0084), do not make sense with respect to a stranded and rehabilitated animal.

Response: The purpose of this Procedural Directive is to explain that NMFS will no longer accept applications that specifically seek to obtain releasable rehabilitated marine mammals. Applicants will be instructed to submit ''take from the wild'' permit applications with all required information for that take activity included in the permit application, as described in the Application Instructions and Supplemental Information for Public Display Permits under the MMPA (OMB No. 0648–0084).

The applications for the three permits NOAA issued authorizing the retention of releasable marine mammals followed the Application Instructions and Supplemental Information for Public Display Permits under the MMPA (OMB No. 0648–0084). These applications addressed all the applicable questions including the status of the affected stocks and the anticipated impacts on the species or stocks. Given that these applications did not propose directly capturing marine mammals from the wild, the applications referenced the authority of the stranding network and their procedures when addressing the questions specifically related to capture from the wild. Under this Procedural Directive, permit applications will continue to address the status of the species and the impacts of the removal of the desired number of animals from the stock or population.

Non-Releasable Rehabilitated Marine Mammals

Comment 14: One commenter recommended NMFS ensure the wording of this procedural directive adequately take into account the practice of declaring healthy ice seals non-releasable if they are removed from their home range for rehabilitation per NOAA's agreement with co-management groups.

Response: This Procedural Directive does not affect NMFS's process for making release determinations and the placement process for non-releasable marine mammals. Additional text was added to the Directive to clarify.

Dated: May 1, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–09611 Filed 5–4–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG066

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Seabird and Pinniped Research Activities in Central California

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received a request from Point Blue Conservation Science (Point Blue) for authorization to take marine mammals incidental to seabird and pinniped research activities in central California. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than June 6, 2018.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.pauline@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/node/23111* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Rob Pauline, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On January 4, 2018, NMFS received a request from Point Blue for an IHA to take marine mammals incidental to seabird and marine mammal research monitoring taking place at three locations in central California. Point Blue's request is for take of California sea lions (*Zalophus californianus*), Pacific harbor seals *(Phoca vitulina*), northern elephant seals (*Mirounga angustirostris*), and Steller sea lions (*Eumetopias jubatus*) by Level B harassment only. Neither Point Blue nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued eight IHAs to Point Blue for similar work from 2006 through 2017 (72 FR 71121; December 14, 2007, 73 FR 77011; December 18, 2008, 75 FR 8677; February 19, 2010, 77 FR 73989; December 7, 2012, 78 FR 66686; November 6, 2013, 80 FR 80321; December 24, 2015, 81 FR 34978; June 1, 2016, 82 FR 31759; July 7, 2017). Point Blue complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHAs and information regarding their monitoring results may be found in the Estimated Take section. The proposed seabird and marine mammal research activities will occur on Southeast Farallon Island (SEFI), Año Nuevo Island (ANI), and Point

Reyes National Seashore (PRNS). Point Blue, along with partners Oikonos Ecosystem Knowledge and PRNS, plan to conduct the proposed activities for one year. These partners are conducting this research under cooperative agreements with the U.S. Fish and Wildlife Service (USFWS) in consultation with the Gulf of the Farallones National Marine Sanctuary. We considered the renewal for request for 2018–2019 activities as adequate and complete on February 28, 2018.

Description of Proposed Activity

Overview

Point Blue proposes to monitor and census seabird colonies; observe seabird nesting habitat; restore nesting burrows; observe breeding elephant and harbor seals; and resupply a field station annually in central California (*i.e.,* SEFI, ANI, and PRNS). The purpose of the seabird research is to continue a 30-year monitoring program of the region's seabird populations. Point Blue's long-term pinniped research program monitors pinniped colonies to understand elephant and harbor seal population dynamics and to contribute to the conservation of both species. Level B take may occur due to incidental disturbance of pinnipeds by researchers during monitoring activities.

Dates and Duration

The proposed authorization would be effective from July 7, 2018 through July 6, 2019. Research on SEFI is conducted year round. Most intertidal areas of the island, where marine mammals are present, are rarely visited in seabird research. Most potential for incidental take will occur at the island's 2 landings, North Landing and East Landing. At SEFI, seabird monitoring sites are visited ~1–3 times per day for a maximum of 500 visits per year. Most seabird monitoring visits are brief (~15 minutes), though seabird observers are present from 2–5 hours daily at North Landing from early April—early August each year to conduct observational studies on breeding common murres. Boat landings to re-supply the field station, lasting 1–3 hours, are conducted once every two weeks. At ANI, research is conducted approximately once/week from April–August, with occasional intermittent visits made during the rest of the year. The maximum number of visits per year would be 20. Landings and visits to nest boxes are brief (~15 minutes).

Research at PRNS is conducted year round, with an emphasis during the seabird nesting season with occasional intermittent visits the rest of the year. The maximum number of visits per year is 20. A component of the seabird research involves habitat restoration and monitoring which requires sporadic visits from September–November, between the seabird breeding season and the elephant seal pupping season. Most areas where research occurs and where marine mammals are present are not ever visited, excepting the landing beaches along Point Reyes Headland.

Specific Geographic Region

Point Blue will conduct their research activities within the vicinity of pinniped haul-out sites in the following locations:

- *South Farallon Islands:* SEFI is located at 37°41′54.32″ N; 123°0′8.33″ W and West End Island. The South Farallon Islands have a land area of approximately 120 acres (0.49 square kilometers (km^2)) and are part of the Farallon National Wildlife Refuge. The islands are located near the edge of the continental shelf 28 miles (mi) (45.1 km) west of San Francisco, CA, and lie within the waters of the Gulf of the Farallones National Marine Sanctuary;
- *Año Nuevo Island:* ANI is located at 37°6′29.25″ N; 122°20′12.20″ W is one-quarter mile (402 meters m) offshore of Año Nuevo Point in San Mateo County, CA. The island lies within the Monterey Bay National Marine Sanctuary and the Año Nuevo State Marine Conservation Area; and
- *Point Reyes National Seashore:* PRNS is approximately 40 miles (64.3 km) north of San Francisco Bay and lies within the Gulf of the Farallones National Marine Sanctuary.

Detailed Description of Specific Activity

Southeast Farallon Islands—Point Blue has conducted year round wildlife research and monitoring activities at SEFI, part of the Farallon National Wildlife Refuge, since 1968. This work is conducted through a collaborative agreement with the USFWS. Research focuses on marine mammals and seabirds and includes procedures involved in maintaining the SEFI field station. These activities may involve the incidental take of marine mammals.

Seabird research activities involve observational and marking (*i.e.,* netting and banding for capture-mark-recapture) studies of breeding seabirds. Occasionally researchers may travel to coastal areas of the island to conduct observational seabird research where non-breeding marine mammals are present, which includes viewing breeding seabirds from an observation blind or censusing shorebirds, and usually involves one or two observers. Access to the refuge involves landing in 14–18 feet (ft) open motorboats, which are hoisted onto the island using a derrick system.

Most intertidal areas of the island, where marine mammals are present, are rarely visited in seabird research. Most potential for incidental take will occur at the island's two landings, North Landing and East Landing. At both landings, research stations are located more than 50 ft above any pinnipeds that may be present and are visited 1–3 times per day. These pinnipeds are primarily California sea lions or northern elephant seals. Harbor seals are also present on these landings to a lesser extent and there are rare instances of Steller sea lions. Boat landings to re-supply the field station, lasting 1–3 hours, are conducted once every two weeks at either the North or East Landing. Activities involve launching of the boat with one operator, with 2–4 other researchers assisting with the operations from land. At East Landing, the primary landing site, all personnel assisting with the landing stay on the loading platform 30 ft above the water. At North Landing, loading operations occur at the water level in the intertidal zone.

Año Nuevo Island—Point Blue has also conducted seabird research and monitoring activities on ANI, part of the Año Nuevo State Reserve, since 1992. Collaborations with Oikonos Ecosystem Knowledge began in 2001 to research seabird burrow nesting habitat quality and restoration. All work is conducted through a collaborative agreement with California State Parks. The island is accessed by a 12 ft Zodiac boat. Non-breeding pinnipeds may occasionally be present on the small beach in the center of the island where the boat is landed. California sea lions may also occasionally be present near a small group of subterranean seabird nest boxes on the island terrace. There are usually 2–3 researchers involved in island visits.

Point Reyes National Seashore—The National Park Service (NPS) conducts research, resource management and routine maintenance services at PRNS. This involves both marine mammal research and seabird research and includes maintaining the facilities around the seashore. Habitat restoration of the seashore occurs and includes restoration and removal of non-native invasive plants and coastal dune habitat. Non-native plant removal is timed to avoid the breeding seasons of pinnipeds; however, on occasion, non-breeding animals may be present at various beaches throughout the year. Additionally, elephant seals will haul out on human structures and block

access to facilities. They are known to haul out on a boat ramp at the Life Boat Station and in various car parking lots around the seashore.

Research along the seashore includes monitoring seabird breeding and roosting colonies. Seabird monitoring usually involves one or two observers. Surveys are conducted by 14–22 ft open motorboats that survey along the shoreline.

Most areas where marine mammals are present are never visited, excepting the landing beaches along Point Reyes headland. In all locations, researchers are located more than 50 ft away from any pinnipeds that may be hauled out. Elephant seals may haul out on boat ramps and parking lots year round.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see ''Proposed Mitigation'' and ''Proposed Monitoring and Reporting'').

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SAR; *www.nmfs.noaa.gov/pr/sars/*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*www.nmfs.noaa.gov/pr/species/mammals/*).

Table 1 lists all species with expected potential for occurrence at SEFI, ANI, and PRNS and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow the Committee on Taxonomy (2017). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. 2016 U.S. Pacific Stock Assessment Report (Carretta *et al.,* 2017) or the 2016 Alaska Stock Assessment Report (Muto *et al.,* 2017). All values presented in Table 1 are the most recent available at the time of publication and are available in the 2016 SARs (Carretta *et al.,* 2017; Muto *et al.,* 2017).

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF STUDY AREAS

Species	Scientific name	Stock	ESA/ MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions)						
California sea lion	*Zalophus californianus* ..	U.S.	-; N	296,750 (n/a; 153,337; 2011).	9,200	389
Steller sea lion	*Eumetopias jubatus*	Eastern U.S.	D; Y	71,562 (n/a; 41,638; 2015).	2,498	108
Family Phocidae (earless seals)						
Harbor seal	*Phoca vitulina richardii* ..	California	-; N	30,968 (0.157; 27,348; 2012).	1,641	43
Northern elephant seal ..	*Mirounga angustirostris*	California breeding stock	-; N	179,000 (n/a; 81,368; 2010).	4,882	8.8

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable [explain if this is the case]

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

Northern Elephant Seal

Northern elephant seals range in the eastern and central North Pacific Ocean, from as far north as Alaska to as far south as Mexico. Northern elephant seals spend much of the year, generally about nine months, in the ocean. They are usually underwater, diving to depths of about 1,000 to 2,500 ft (330–800 m) for 20- to 30-minute intervals with only short breaks at the surface. They are rarely seen out at sea for this reason. While on land, they prefer sandy beaches.

The northern elephant breeding population is distributed from central Baja California, Mexico to the Point Reyes Peninsula in northern California. Along this coastline, there are 13 major breeding colonies. Northern elephant seals breed and give birth primarily on offshore islands (Stewart *et al.,* 1994), from December to March (Stewart and Huber, 1993). Males feed near the eastern Aleutian Islands and in the Gulf of Alaska, and females feed farther

south, south of 45° N (Stewart and Huber, 1993; Le Boeuf *et al.,* 1993). Adults return to land between March and August to molt, with males returning later than females. Adults return to their feeding areas again between their spring/summer molting and their winter breeding seasons.

At SEFI, the population consists of approximately 500 animals (FNMS 2013). Northern elephant seals began recolonizing the South Farallon Islands in the early 1970s (Stewart *et al.,* 1994) at which time the colony grew rapidly. In 1983 a record 475 pups were born on the South Farallones (Stewart *et al.,* 1994). Since then, the size of the South Farallones colony has declined, stabilizing in the early 2000s and then declining further over the past 6 years (USFWS 2013). In 2012, a total of 90 cows were counted on the South Farallones, and 60 pups were weaned (USFWS 2013). Point Blue's average monthly counts from 2000 to 2009 ranged from 20 individuals in July to nearly 500 individuals in November (USFWS 2013).

Northern elephant seals are present on the islands and in the waters surrounding the South Farallones year-round for either breeding or molting; however, they are more abundant during breeding and peak molting seasons (Le Boeuf and Laws, 1994; Sydeman and Allen, 1999). They live and feed in deep, offshore waters the remainder of the year.

In mid-December, adult males begin arriving on the South Farallones, closely followed by pregnant females on the verge of giving birth. Females give birth to a single pup, generally in late December or January (Le Boeuf and Laws, 1994) and nurse their pups for approximately four weeks (Reiter *et al.,* 1991). Upon pup weaning, females mate with an adult male and then depart the islands. The last adult breeders depart the islands in mid-March. The spring peak of elephant seals on the rookery occurs in April, when females and immature seals (approximately one to four years old) arrive at the colony to molt (a one-month process) (USFWS 2013). The year's new pups remain on the island throughout both of these peaks, generally leaving by the end of April (USFWS 2013).

The lowest numbers of elephant seals present on the rookery occurs during June, July, and August, when sub-adult and adult males molt. Another peak of young seals return to the rookery for a haul-out period in October, and at that time some individuals undergo partial molt (Le Boeuf and Laws, 1994). At ANI the population ranges from 900 to 1,000 adults.

California Sea Lion

California sea lion breeding areas are on islands located in southern California, in western Baja California, Mexico, and the Gulf of California. Rookery sites in southern California are limited to the San Miguel Islands and the southerly Channel Islands of San Nicolas, Santa Barbara, and San Clemente (Carretta *et al.,* 2017). Males establish breeding territories during May through July on both land and in the water. Females come ashore in mid-May and June where they give birth to a single pup approximately four to five days after arrival and will nurse pups for about a week before going on their first feeding trip. Females will alternate feeding trips with nursing bouts until the pup is weaned between four and 10 months of age (NMML 2010).

Adult and juvenile males will migrate as far north as British Columbia, Canada while females and pups remain in southern California waters in the non-breeding season. In warm water (El Niño) years, some females are found as far north as Washington and Oregon, presumably following prey.

On the Farallon Islands, California sea lions haul out in many intertidal areas year round, fluctuating from several hundred to several thousand animals. California sea lions at PRNS haul out at only a few locations, but will occur on human structures such as boat ramps. The annual population averages around 300 to 500 during the fall through spring months, although on occasion, several thousand sea lions can arrive depending upon local prey resources (S. Allen, unpublished data). On ANI, California sea lions may haul out at one of eight beach areas on the perimeter of the island. The island's average population ranges from 4,000 to 9,500 animals (M. Lowry, unpublished data).

Pacific Harbor Seal

Harbor seals inhabit near-shore coastal and estuarine areas from Baja California, Mexico, to the Pribilof Islands in Alaska. Pacific harbor seals are divided into two subspecies: *P.* v. *stejnegeri* in the western North Pacific, near Japan, and *P.* v. *richardsi* in the northeast Pacific Ocean. The California stock ranges from north of Baja, California to the Oregon-California border. Other stocks recognized along the U.S. west coast include: (1) Southern Puget Sound; (2) Washington Northern Inland Waters; (3) Hood Canal; and (4) Oregon/Washington Coast.

In California, 400–600 harbor seal haul-out sites are widely distributed along the mainland and offshore islands, and include rocky shores, beaches and intertidal sandbars (Lowry *et al.,* 2008). On the Farallon Islands, approximately 40 to 120 Pacific harbor seals haul out in the intertidal areas (Point Blue unpublished data). Harbor seals at PRNS haul out at nine locations with an annual population of up to 4,000 animals (M. Lowry, unpublished data). On ANI, harbor seals may haul out at one of eight beach areas on the perimeter of the island and the island's average population ranges from 100 to 150 animals (M. Lowry, unpublished data).

Steller Sea Lion

Steller sea lions consist of two distinct population segments: The western and eastern distinct population segments (DPS) divided at 144° W longitude (Cape Suckling, Alaska). The western segment of Steller sea lions inhabit central and western Gulf of Alaska, Aleutian Islands, as well as coastal waters and breed in Asia (*e.g.,* Japan and Russia). The eastern segment includes sea lions living in southeast Alaska, British Columbia, California, and Oregon. The eastern DPS includes animals born east of Cape Suckling, AK (144° W) and the latest abundance estimate for the stock is 71,562 animals (Muto *et al.,* 2017).

Despite the wide-ranging movements of juveniles and adult males in particular, exchange between rookeries by breeding adult females and males (other than between adjoining rookeries) appears low, although males have a higher tendency to disperse than females (NMFS, 1995; Trujillo *et al.,* 2004; Hoffman *et al.,* 2006). A northward shift in the overall breeding distribution has occurred, with a contraction of the range in southern California and new rookeries established in southeastern Alaska (Pitcher *et al.,* 2007).

An estimated 50–150 Steller sea lions are located along the Farallon Islands while 400–600 may be found on ANI (Point Blue, unpublished data; Lowry, unpublished data). None are present at PRNS (NPS, unpublished data). Overall, counts of non-pups at trend sites in California and Oregon have been relatively stable or increasing slowly since the 1980s (Muto *et al.,* 2017).

Point Blue estimates that between 50 and 150 Steller sea lions live on the Farallon Islands. On SEFI, the abundance of females declined an average of 3.6 percent per year from 1974 to 1997 (Sydeman and Allen, 1999).

NMFS' Southwest Fisheries Science Center estimates between 400 and 600 live on ANI (Point Blue unpublished data, 2008; Southwest Fisheries Science

Center unpublished data, 2008). At ANI, a steady decline in ground counts started around 1970, and there was an 85 percent reduction in the breeding population by 1987 (LeBoeuf *et al.,* 1991). Pup counts at ANI declined five percent annually through the 1990s and stabilized between 2001 and 2005 (M. Lowry, SWFSC unpublished data). Pups have not been born at PRNS since the 1970s and Steller sea lions are seen in very low numbers there currently (S. Allen, unpublished data). SEFI is one of two breeding colonies at the southern end of the Steller sea lion's range. On the Farallon and Año Nuevo Islands, Steller sea lion breeding colonies are located in closed areas where researchers never visited, eliminating any risk of disturbing breeding animals.

All species that could potentially occur in the proposed survey areas are included in Table 1.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The ''Estimated Take by Incidental Harassment'' section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis and Determination'' section considers the content of this section, the ''Estimated Take by Incidental Harassment'' section, and the ''Proposed Mitigation'' section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Visual and acoustic stimuli generated by the appearance of researchers and motorboat operations may have the potential to cause Level B harassment of pinnipeds hauled out on SEFI, ANI, or PRNS. This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (*e.g.,* personnel presence and motorboats) have been observed to impact marine mammals. This discussion may also include reactions that we consider to rise to the level of a take and those that we do not consider to rise to the level of a take. This section is intended as a background of potential effects and does not consider either the specific manner in which this activity will be carried out or the mitigation that will be implemented, and how either of those will shape the anticipated impacts from this specific activity.

The appearance of researchers may have the potential to cause Level B harassment of any pinnipeds hauled out at survey sites. Disturbance may result in reactions ranging from an animal simply becoming alert to the presence of researchers (*e.g.,* turning the head, assuming a more upright posture) to flushing from the haul-out site into the water. NMFS does not consider the lesser reactions to constitute behavioral harassment, or Level B harassment take. NMFS rather assumes that pinnipeds that flee some distance or change the speed or direction of their movement in response to the presence of researchers are behaviorally harassed, and thus subject to Level B taking. Animals that respond to the presence of researchers by becoming alert, but do not move or change the nature of locomotion as described, are not considered to have been subject to behavioral harassment. A more detailed description later in the document in Table 4.

Reactions to human presence, if any, depend on species, state of maturity, experience, current activity, reproductive state, time of day, and many other factors (Richardson *et al.,* 1995; Southall *et al.,* 2007; Weilgart 2007). These behavioral reactions from marine mammals are often shown as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior; avoidance of areas; and/or flight responses (*e.g.,* pinnipeds flushing into the water from haulouts or rookeries). If a marine mammal does react briefly to human presence by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if visual stimuli from human presence displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder 2007; Weilgart, 2007). Numerous studies have shown that human activity can flush harbor seals off haul-out sites (Allen *et al.,* 1985; Calambokidis *et al.,* 1991; Suryan and Harvey, 1999). The Hawaiian monk seal (*Neomonachus schauinslandi*) has been shown to avoid beaches that have been disturbed often by humans (Kenyon 1972). In one case, human disturbance appeared to cause Steller sea lions to desert a breeding area at Northeast Point on St. Paul Island, Alaska (Kenyon 1962).

In cases where vessels actively approached marine mammals (*e.g.,* whale watching or dolphin watching boats), scientists have documented that animals exhibit altered behavior such as increased swimming speed, erratic movement, and active avoidance behavior (Acevedo, 1991; Trites and Bain, 2000; Williams *et al.,* 2002; Constantine *et al.,* 2003), reduced blow interval, disruption of normal social behaviors (Lusseau 2003; 2006), and the shift of behavioral activities which may increase energetic costs (Constantine *et al.,* 2003).

In 1997, Henry and Hammil (2001) conducted a study to measure the impacts of small boats (*i.e.,* kayaks, canoes, motorboats and sailboats) on harbor seal haul-out behavior in Metis Bay, Quebec, Canada. During that study, the authors noted that the most frequent disturbances (n = 73) were caused by lower speed, lingering kayaks, and canoes (33.3 percent) as opposed to motorboats (27.8 percent) conducting high-speed passes. The seal's flight reactions could be linked to a surprise factor by kayaks and canoes, which approach slowly, quietly, and low on the water making them look like predators. However, the authors note that once the animals were disturbed, there did not appear to be any significant lingering effect on the recovery of numbers to their pre-disturbance levels. In conclusion, the study showed that boat traffic at current levels had only a temporary effect on the haul-out behavior of harbor seals in the Metis Bay area.

In 2004, Acevedo-Gutierrez and Johnson (2007) evaluated the efficacy of buffer zones for watercraft around harbor seal haul-out sites on Yellow Island, Washington. The authors estimated the minimum distance between the vessels and the haul-out sites; categorized the vessel types; and evaluated seal responses to the disturbances. During the course of the seven-weekend study, the authors recorded 14 human-related disturbances that were associated with stopped powerboats and kayaks. During these events, hauled out seals became noticeably active and moved into the water. The flushing occurred when stopped kayaks and powerboats were at distances as far as 453 and 1,217 ft (138 and 371 m) respectively. The authors note that the seals were unaffected by passing powerboats, even those approaching as close as 128 ft (39 m), possibly indicating that the animals had become tolerant of the brief presence of the vessels and ignored them. The

authors reported that on average, the seals quickly recovered from the disturbances and returned to the haul-out site in less than or equal to 60 minutes. Seal numbers did not return to pre-disturbance levels within 180 minutes of the disturbance less than one quarter of the time observed. The study concluded that the return of seal numbers to pre-disturbance levels and the relatively regular seasonal cycle in abundance throughout the area counter the idea that disturbances from powerboats may result in site abandonment (Johnson and Acevedo-Gutierrez, 2007). As a general statement from the available information, pinnipeds exposed to intense (approximately 110 to 120 decibels re: 20 µPa) non-pulsed sounds often leave haul-out areas and seek refuge temporarily (minutes to a few hours) in the water (Southall *et al.,* 2007).

The potential for striking marine mammals is a concern with vessel traffic. Typically, the reasons for vessel strikes are fast transit speeds, lack of maneuverability, or not seeing the animal because the boat is so large. Point Blue's researchers will access areas at slow transit speeds in small boats that are easily maneuverable, minimizing any chance of an accidental strike.

There are other ways in which disturbance, as described previously, could result in more than Level B harassment of marine mammals. They are most likely to be consequences of stampeding, a potentially dangerous occurrence in which large numbers of animals succumb to mass panic and rush away from a stimulus. These situations are: (1) Falling when entering the water at high-relief locations; (2) extended separation of mothers and pups; and (3) crushing of pups by larger animals during a stampede. However, NMFS does not expect any of these scenarios to occur at SEFI, ANI, or PRNS. There is the risk of injury if animals stampede towards shorelines with precipitous relief (*e.g.,* cliffs). Researchers will take precautions, such as moving slowly and staying close to the ground, to ensure that flushes do not result in a stampede of pinnipeds heading to the sea. Point Blue reports that stampedes are extremely rare at their survey locations. Furthermore, no research activities would occur at or near pinniped rookeries. Breeding animals are concentrated in areas where researchers would not visit so NMFS does not expect mother and pup separation or crushing of pups during flushing. Furthermore, if pups should be present at Point Blue, researchers will avoid visiting that particular site.

Given the nature of the proposed activities (*i.e.* animal observations from a distance and limited motorboat operations) in conjunction with proposed mitigation measures, NMFS is confident that any anticipated effects would be in the form of behavioral disturbance only. NMFS considers the risk of injury, serious injury, or mortality to marine mammals to be very low.

There are no habitat modifications associated with the proposed activity other than the presence of existing observation blinds by researchers to monitor animals. These blinds disturb only a few square feet of habitat. The presence of the blinds will likely result in a net decrease in disturbance since the researchers will only be visible briefly as they enter and exit the blind. Thus, NMFS does not expect that the proposed activity would have any effects on marine mammal habitat and NMFS expects that there will be no long- or short-term physical impacts to pinniped habitat on SEFI, ANI, or PRNS.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to pedestrian researchers. Based on the nature of the activity, Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated. NMFS bases these take estimates on historical data from the five previous monitoring reports to generate 95 percent confidence interval maximums (assuming normal distribution) using STATA, a general-purpose statistical computer software package. Results are shown in Table 2. Takes recorded in all previous monitoring reports were based on occurrences that are consistent with Levels 2 and 3 of the three-point-scale (See Table 4). Note that Point Blue has never exceeded authorized take levels under any previously issued IHA. For California sea lions and harbor seals, NMFS elected to use the values projected as shown in Table 2. However, since the projected take numbers for northern elephant seals and Steller sea lions were very close to recorded takes in 2017–2018, NMFS increased the proposed take numbers for these species by 20 percent over the actual 2017–2018 take numbers shown in Table 2. This provides a buffer so Point Blue can continue their work if recorded takes for those two species exceeded take numbers generated by the STATA program. Proposed authorized take numbers are shown in Table 3.

TABLE 2—PAST REPORTED TAKE OBSERVATIONS AND ESTIMATED TAKE FOR PROPOSED 2018–2019 POINT BLUE ACTIVITIES ACCORDING TO STATISTICAL ANALYSIS

Species	Reported take observations from past seasons [1]					Projected Take 2018–2019 IHA
	IHA (2013–2014)	IHA (2014–2015)	IHA (2015–2016)	IHA (2016–2017)	IHA (2017–2018	
California Sea Lions	3,610	2,254	4,646	36,397 [1]	22,612	32,623
Northern Elephant Seals	67	30	97	169	198	199
Harbor Seals	109	141	259	292	234	304
Steller Sea Lions (E–DPS)	4	12	6	31	35	36

[1] Large increase in California sea lions likely due to El Niño event.

TABLE 3—POPULATION ABUNDANCE ESTIMATES, TOTAL PROPOSED LEVEL B TAKE, AND PERCENTAGE OF POPULATION THAT MAY BE TAKEN

Species	Stock	Stock abundance	Total proposed Level B take	Percentage of stock or population
California sea lion	U.S.	296,750	32,623	10.9
Northern elephant seal	California breeding stock	179,000	238	0.13
Harbor seal	California	30,968	304	0.98
Steller sea lion	Eastern U.S.	71,562	42	0.05

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned); and

(2) the practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

Point Blue has based the mitigation measures, which they will employ during the research, on the implementation of protocols used during previous Point Blue research activities under previous authorizations for these activities. Note that Point Blue and NMFS have refined mitigation requirements over the years in an effort to reduce behavioral disturbance impacts to marine mammals.

To reduce the potential for disturbance from acoustic and visual stimuli associated with survey activities Point Blue will implement the following mitigation measures for marine mammals:

(1) Slow approach to beaches for boat landings to avoid stampede, provide animals opportunity to enter water, and avoid vessel strikes;

(2) Observe a site from a distance, using binoculars if necessary, to detect any marine mammals prior to approach to determine if mitigation is required (*i.e.,* site surveys will not be conducted if northern fur seals, or Guadalupe fur seals are present; if other pinnipeds are present, researchers will approach with caution, walking slowly, quietly, and close to the ground to avoid surprising any hauled-out individuals and to reduce flushing/stampeding of individuals);

(3) Avoid pinnipeds along access ways to sites by locating and taking a different access way. Researchers will keep a safe distance from and not approach any marine mammal while conducting research, unless it is absolutely necessary to flush a marine mammal in order to continue conducting research (*i.e.,* if a site cannot be accessed or sampled due to the presence of pinnipeds);

(4) Avoid visits to sites when pups are present or when species for which authorization has not been granted (*e.g.,* northern fur seals and Guadalupe fur seals) are present;

(5) Monitor for offshore predators and do not approach hauled out pinnipeds if great white sharks (*Carcharodon carcharias*) or killer whales (*Orcinus orca*) are present. If Point Blue and/or its designees see pinniped predators in the area, they must not disturb the pinnipeds until the area is free of predators;

(6) Keep voices hushed and bodies low to the ground in the visual presence of pinnipeds;

(7) Conduct seabird observations at North Landing on SEFI in an observation blind, shielded from the view of hauled out pinnipeds;

(8) Crawl slowly to access seabird nest boxes on ANI if pinnipeds are within view;

(9) Coordinate research visits to intertidal areas of SEFI (to reduce potential take) and coordinate research goals for ANI to minimize the number of trips to the island;

(10) Require beach landings on ANI only occur after any pinnipeds that might be present on the landing beach have entered the water; and

(11) Have the lead biologist serve as an observer to record incidental take.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has determined that the prescribed mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth, requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Point Blue will contribute to the knowledge of pinnipeds in California by noting observations of: (1) Unusual behaviors, numbers, or distributions of pinnipeds, such that any potential follow-up research can be conducted by the appropriate personnel; (2) tag-bearing pinnipeds or carcasses, allowing transmittal of the information to appropriate agencies and personnel; and (3) rare or unusual species of marine mammals for agency follow-up.

Required monitoring protocols for Point Blue will include the following:

(1) Record of date, time, and location (or closest point of ingress) of each visit to the research site;

(2) Composition of the marine mammals sighted, such as species, gender and life history stage (*e.g.,* adult, sub-adult, pup);

(3) Information on the numbers (by species) of marine mammals observed during the activities;

(4) Estimated number of marine mammals (by species) that may have been harassed during the activities;

(5) Behavioral responses or modifications of behaviors that may be attributed to the specific activities and a description of the specific activities occurring during that time (*e.g.,* pedestrian approach, vessel approach); and

(6) Information on the weather, including the tidal state and horizontal visibility.

For consistency, any reactions by pinnipeds to researchers will be recorded according to a three-point scale shown in Table 4. Note that only observations of disturbance noted in Levels 2 and 3 should be recorded as takes.

TABLE 4—LEVELS OF PINNIPED BEHAVIORAL DISTURBANCE

Level	Type of response	Definition
1	Alert	Seal head orientation or brief movement in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, changing from a lying to a sitting position, or brief movement of less than twice the animal's body length.
2*	Movement	Movements in response to the source of disturbance, ranging from short withdrawals at least twice the animal's body length to longer retreats over the beach, or if already moving a change of direction of greater than 90 degrees.
3*	Flush	All retreats (flushes) to the water.

*Only observations of disturbance Levels 2 and 3 are recorded as takes.

This information will be incorporated into a monitoring report for NMFS. The monitoring report will cover the period from January 1, 2018 through December 31, 2018. NMFS has requested that Point Blue submit annual monitoring report data on a calendar year schedule, regardless of the current IHA's initiation or expiration dates. This will ensure that data from all consecutive months will be collected and, therefore, can be analyzed to estimate authorized take for future IHA's regardless of the existing IHA's issuance date. Point Blue will submit a draft monitoring report to NMFS Office of Protected Resources by April 1, 2018. A final report will be prepared and submitted within 30 days following resolution of any comments on the draft report from NMFS. If no comments are received from NMFS, the draft final report will be considered to be the final report. This report must contain the informational elements described above, at minimum.

Point Blue must also report observations of unusual pinniped behaviors, numbers, or distributions and tag-bearing carcasses to NMFS West Coast Region office.

If at any time the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as an injury (Level A harassment), serious injury, or mortality, Point Blue will immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS. The report must include the following information:

(1) Time and date of the incident;

(2) Description of the incident;

(3) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

(4) Description of all marine mammal observations in the 24 hours preceding the incident;

(5) Species identification or description of the animal(s) involved;

(6) Fate of the animal(s); and

(7) Photographs or video footage of the animal(s).

Activities will not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Point Blue to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Point Blue may not resume the activities until notified by NMFS.

In the event that an injured or dead marine mammal is discovered and it is determined that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), Point Blue will immediately report the

incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS. The report must include the same information identified in the paragraph above IHA. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Point Blue to determine whether additional mitigation measures or modifications to the activities are appropriate.

In the event that an injured or dead marine mammal is discovered and it is determined that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Point Blue will report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. Point Blue will provide photographs or video footage or other documentation of the stranded animal sighting to NMFS. Activities may continue while NMFS reviews the circumstances of the incident.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

For reasons stated previously in this document and based on the following factors, NMFS does not expect Point Blue's specified activities to cause long-term behavioral disturbance that would negatively impact an individual animal's fitness, or result in injury, serious injury, or mortality. Although Point Blue's survey activities may disturb marine mammals, NMFS expects those impacts to occur to localized groups of animals at or near survey sites. Behavioral disturbance would be limited to short-term startle responses and localized behavioral changes due to the short duration (ranging from <15 minutes for visits at most locations up to 2–5 hours from April-August at SEFI) of the research activities. At some locations, where resupply activities occur, visits will occur once every two weeks. Minor and brief responses including short-duration startle reactions, are not likely to constitute disruption of behavioral patterns, such as migration, nursing, breeding, feeding, or sheltering. These short duration disturbances (in many cases animals will return in 30 minutes or less) will generally allow marine mammals to reoccupy haulouts relatively quickly; therefore, these disturbances would not be anticipated to result in long-term disruption of important behaviors. No surveys will occur at or near rookeries as researchers will have limited access to SEFI, ANI, and PRNS during the pupping season and will not approach sites should pups be observed. Furthermore, breeding animals tend to be concentrated in areas that researchers are not scheduled to visit. Therefore, NMFS does not expect mother and pup separation or crushing of pups during stampedes.

Level B behavioral harassment of pinnipeds may occur during the operation of small motorboats. However, exposure to boats and associated engine noise would be brief and would not occur on a frequent basis. Results from studies demonstrate that pinnipeds generally return to their sites and do not permanently abandon haul-out sites after exposure to motorboats. The chance of a vessel strike is very low due to small boat size and slow transit speeds. Researchers will delay ingress into the landing areas until after the pinnipeds enter the water and will cautiously operate vessels at slow speeds.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized.
- Only limited behavioral disturbance in the form of short-duration startle reactions is expected while mitigation requirements employed by researchers (*e.g.* move slowly, use hushed voices) should further decrease disturbance levels.
- There is no activity near rookeries and researchers will avoid pups.
- There is likely to be limited impact from boats due to their small size, maneuverability and the requirement to delay ingress until after hauled out pinnipeds have entered the water.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

As mentioned previously, NMFS estimates that four marine mammal stocks could potentially be affected by Level B harassment under the proposed authorization. For each stock, these numbers are small relative to the population size. As shown previously in Table 3, these incidental harassment numbers represent approximately 10.9 percent of the U.S. stock of California sea lion, 0.98 percent of the California stock of Pacific harbor seal, 0.13 percent of the California breeding stock of northern elephant seal, and 0.05 percent of the eastern distinct population segment of Steller sea lion. Note that the number of individual marine mammals

taken is assumed to be less than the take estimate (number of exposures) since we assume that the same animals may be behaviorally harassed over multiple days.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has preliminarily determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with West Coast Region Protected Resources Division Office, whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Point Blue Conservation Science for conducting research surveys at SEFI, ANI, and PRNS from June July 7, 2018 through July 6, 2019 provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This Incidental Harassment Authorization (IHA) is valid for a period of one year from July 7, 2018 through July 6, 2019.

2. This IHA is valid only for specified activities associated with seabird research and resupply activities located on or near Southeast Farallon Island, Año Nuevo Island, and Point Reyes National Seashore in central California.

3. General Conditions.

(a) A copy of this IHA must be in the possession of Point Blue, its designees, and work crew personnel operating under the authority of this IHA.

(b) The incidental taking of marine mammals, by Level B harassment only, is limited to the following species and associated authorized take numbers as shown below:

(i) 304 harbor seal; *(Phoca vitulina richardii);*

(ii) 32,623 California sea lions *(Zalophus californianus);*

(iii) 42 Steller sea lions *(Eumetopias jubatus);* and

(iv) 238 northern elephant seals *(Mirounga angustirostris).*

(c) The taking by injury (Level A harassment), serious injury, or death of any of the species listed in condition 3(b) of the Authorization or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

4. Mitigation Measures.

The holder of this Authorization is required to implement the following mitigation measures:

(a) Researchers shall slowly approach beaches for boat landings to avoid stampede, provide animals opportunity to enter water, and avoid vessel strikes.

(b) Researchers shall observe a site from a distance, using binoculars if necessary, to detect any marine mammals prior to approach to determine if mitigation is required (*i.e.,* site surveys shall not be conducted if northern fur seals, or Guadalupe fur seals are present; if other pinnipeds are present, researchers shall approach with caution, walking slowly, quietly, and close to the ground to avoid surprising any hauled-out individuals and to reduce flushing/stampeding of individuals).

(c) Researchers shall avoid pinnipeds along access ways to sites by locating and taking a different access way. Researchers shall keep a safe distance from and not approach any marine mammal while conducting research, unless it is absolutely necessary to flush a marine mammal in order to continue conducting research (*i.e.,* if a site cannot be accessed or sampled due to the presence of pinnipeds).

(d) Researchers shall avoid visits to sites when pups are present or when species for which authorization has not been granted (*e.g.,* northern fur seals and Guadalupe fur seals) are present.

(e) Researchers shall monitor for offshore predators and shall not approach hauled-out pinnipeds if great white sharks *(Carcharodon carcharias)* or killer whales *(Orcinus area)* are observed. If Point Blue and/or its designees see pinniped predators in the area, they must not disturb the pinnipeds until the area is free of predators.

(f) Researchers shall keep voices hushed and bodies low to the ground in the visual presence of pinnipeds.

(g) Researchers shall conduct seabird observations at North Landing on Southeast Farallon Island in an observation blind, shielded from the view of hauled out pinnipeds.

(h) Researchers shall crawl slowly to access seabird nest boxes on Año Nuevo Island if pinnipeds are within view.

(i) Researchers shall coordinate research visits to intertidal areas of Southeast Farallon Island (to reduce potential take) and coordinate research goals for Año Nuevo Island to minimize the number of trips to the island.

(j) Beach landings shall be required on Año Nuevo Island and shall only occur after any pinnipeds that might be present on the landing beach have entered the water.

(k) The lead biologist shall serve as an observer to record incidental take.

5. Monitoring.

The holder of this IHA is required to:

(a) Record the date, time, and location (or closest point of ingress) of each visit to the research site.

(b) Collect the following information for each visit:

(i) Composition of the marine mammals sighted, such as species, gender and life history stage *(e.g.,* adult, sub-adult, pup);

(ii) Information on the numbers (by species) of marine mammals observed during the activities;

(iii) Estimated number of marine mammals (by species) that may have been harassed during the activities;

(iv) Behavioral responses or modifications of behaviors that may be attributed to the specific activities and a description of the specific activities occurring during that time *(e.g.,* pedestrian approach, vessel approach); and

(v) Information on the weather, including the tidal state and horizontal visibility.

(c) Researchers shall record marine mammal disturbances according to a three-point scale of intensity including:

(i) Seal head orientation or brief movement in response to disturbance, which may include turning head

towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, changing from a lying to a sitting position, or brief movement of less than twice the animal's body length ''alert'';

(ii) Movements in response to source of disturbance, ranging from short withdrawals at least twice the animal's body length to longer retreats over the beach, or if already moving a change of direction of greater than 90 degrees, ''movement''; and

(iii) All retreats (flushes) to the water, ''flush''.

(iv) Observations of disturbance Levels (ii) and (iii) shall be recorded as takes.

(d) If applicable, note observations of marked or tag-bearing pinnipeds or carcasses, as well as any rare or unusual species of marine mammal which should be reported to the West Coast Regional Office.

(e) If applicable, note the presence of any offshore predators (date, time, number, and species).

6. Reporting.

The holder of this Authorization is required to:

(a) Report observations of unusual behaviors or numbers of pinnipeds to the NMFS West Coast Region Office so that the appropriate personnel NMFS personnel may conduct any potential follow-up observations.

(b) Submit a draft monitoring report to NMFS Office of Protected Resources by April 1, 2018 covering the time period of January 1, 2018 through December 31, 2018. A final report shall be prepared and submitted within 30 days following resolution of any comments on the draft report from NMFS. If no comments are received from NMFS, the draft final report will be considered to be the final report.

(c) Reporting injured or dead marine mammals:

(i) In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as an injury (Level A harassment), serious injury, or mortality, Point Blue shall immediately cease the specified activities and report the incident to the Incidental Take Program Supervisor, Permits and Conservation Division, Office of Protected Resources, and the West Coast Regional Stranding Coordinator. The report must include the following information:

1. Time and date of the incident;

2. Description of the incident;

3. Environmental conditions *(e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

4. Description of all marine mammal observations in the 24 hours preceding the incident;

5. Species identification or description of the animal(s) involved;

6. Fate of the animal(s); and

7. Photographs or video footage of the animal(s).

8. Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with Point Blue to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Point Blue may not resume their activities until notified by NMFS.

(ii) In the event that Point Blue discovers an injured or dead marine mammal, and the lead observer determines that the cause of the injury or death is unknown and the death is relatively recent *(e.g.,* in less than a modest state of decomposition), Point Blue shall immediately report the incident to the NMFS contacts listed in 6(c)(i). The report must include the same information identified in 6(c)(i). Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Point Blue to determine whether additional mitigation measures or modifications to the activities are appropriate.

(iii) In the event that Point Blue discovers an injured or dead marine mammal, and the lead observer determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Point Blue shall report the incident to the NMFS contacts listed in 6(c)(i). Point Blue shall provide photographs, video footage or other documentation of the stranded animal sighting to NMFS.

7. This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if NMFS determines the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed action. We also request comment on the potential for renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

On a case-by-case basis, NMFS may issue a second one-year IHA without additional notice when 1) another year of identical or nearly identical activities as described in the Specified Activities section is planned or 2) the activities would not be completed by the time the IHA expires and a second IHA would allow for completion of the activities beyond that described in the Dates and Duration section, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to expiration of the current IHA.
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted beyond the initial dates either are identical to the previously analyzed activities or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, take estimates, or mitigation and monitoring requirements.

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

- Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures remain the same and appropriate, and the original findings remain valid.

Dated: May 2, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–09610 Filed 5–4–18; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 17 May 2018, at 9:00 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW, Washington DC 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our website: *www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed

to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *staff@cfa.gov;* or by calling 202–504–2200.

Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated: April 25, 2018 in Washington, DC.

Thomas Luebke,

Secretary.

[FR Doc. 2018–09334 Filed 5–4–18; 8:45 am]

BILLING CODE 6330–01–M

DELAWARE RIVER BASIN COMMISSION

Notice of Public Hearing and Business Meeting

May 16 and June 13, 2018.

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, May 16, 2018. A business meeting will be held the following month on Wednesday, June 13, 2018. The hearing and meeting are open to the public and will be held at the West Trenton Volunteer Fire Company Ballroom, 40 West Upper Ferry Road, West Trenton, New Jersey.

Public Hearing. The public hearing on May 16, 2018 will begin at 1:30 p.m. Hearing items subject to the Commission's review will include draft dockets for withdrawals, discharges, and other water-related projects, as well as resolutions to: (a) Adopt the Commission's annual Current Expense and Capital Budgets for the fiscal year ending June 30, 2019 (July 1, 2018 through June 30, 2019); (b) apportion among the signatory parties the amounts required for the support of the Current Expense and Capital Budgets for the fiscal year ending June 30, 2019 (July 1, 2018 through June 30, 2019); (c) clarify and restate the Commission's policy for the replacement of water consumptively used by electric generating or cogenerating facilities during critical hydrologic conditions; and (d) authorize the Executive Director to enter into a contract for professional engineering services for technical evaluations and cost estimations for upgrades of wastewater treatment plants discharging to the Delaware River Estuary.

The list of projects scheduled for hearing, including project descriptions, and the text of the proposed resolutions will be posted on the Commission's website, *www.drbc.net,* in a long form of this notice at least ten days before the hearing date.

Written comments on matters scheduled for hearing on May 16 will be accepted through 5:00 p.m. on May 21.

The public is advised to check the Commission's website periodically prior to the hearing date, as items scheduled for hearing may be postponed if additional time is deemed necessary to complete the Commission's review, and items may be added up to ten days prior to the hearing date. In reviewing docket descriptions, the public is also asked to be aware that project details commonly change in the course of the Commission's review, which is ongoing.

Public Meeting. The public business meeting on June 13, 2018 will begin at 10:30 a.m. and will include: adoption of the Minutes of the Commission's March 14, 2018 Business Meeting, announcements of upcoming meetings and events, a report on hydrologic conditions, reports by the Executive Director and the Commission's General Counsel, and consideration of any items for which a hearing has been completed or is not required. The latter are expected to include resolutions: (a) Authorizing the Executive Director to revise the *Administrative Manual—By-Laws, Management and Personnel;* and (b) providing for election of the Commission Chair, Vice Chair and Second Vice Chair for the year commencing July 1, 2018 and ending June 30, 2019.

After all scheduled business has been completed and as time allows, the Business Meeting will be followed by up to one hour of Open Public Comment, an opportunity to address the Commission on any topic concerning management of the basin's water resources, outside the context of a duly noticed, on-the-record public hearing.

There will be no opportunity for additional public comment for the record at the June 13 Business Meeting on items for which a hearing was completed on May 16 or a previous date. Commission consideration on June 13 of items for which the public hearing is closed may result in approval of the item (by docket or resolution) as proposed, approval with changes, denial, or deferral. When the Commissioners defer an action, they may announce an additional period for written comment on the item, with or without an additional hearing date, or they may take additional time to consider the input they have already received without requesting further public input. Any deferred items will be considered for action at a public meeting of the Commission on a future date.

Advance Sign-Up for Oral Comment. Individuals who wish to comment on the record during the public hearing on May 16 or to address the Commissioners informally during the Open Public Comment portion of the meeting on June 13 as time allows, are asked to sign-up in advance through EventBrite. Links to EventBrite for the Public Hearing and the Business Meeting are available at *drbc.net.* For assistance, please contact Ms. Paula Schmitt of the Commission staff, at *paula.schmitt@drbc.nj.gov.*

Submitting Written Comment. Written comment on items scheduled for hearing may be made through SmartComment, the web-based comment system introduced by the Commission, a link to which is provided at *drbc.net.* Use of SmartComment ensures that all submissions are captured in a single location and their receipt is acknowledged. Exceptions to the use of SmartComment are available based on need, by writing to the attention of the Commission Secretary, DRBC, P.O. Box 7360, 25 Cosey Road, West Trenton, NJ 08628. For assistance, please contact Paula Schmitt at *paula.schmitt@drbc.nj.gov.*

Accommodations for Special Needs. Individuals in need of an accommodation as provided for in the Americans with Disabilities Act who wish to attend the meeting or hearing should contact the Commission Secretary directly at 609–883–9500 ext. 203 or through the Telecommunications Relay Services (TRS) at 711, to discuss how we can accommodate your needs.

Additional Information, Contacts. Additional public records relating to hearing items may be examined at the Commission's offices by appointment by contacting Denise McHugh, 609–883–9500, ext. 240. For other questions concerning hearing items, please contact Judith Scharite, Project Review Section assistant at 609–883–9500, ext. 216.

Dated: April 30, 2018.

Pamela M. Bush,

Commission Secretary and Assistant General Counsel.

[FR Doc. 2018–09563 Filed 5–4–18; 8:45 am]

BILLING CODE 6360–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Assistance for Arts Education Program—Arts in Education National Program

AGENCY: Office of Innovation and Improvement, Department of Education

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2018 for the Assistance for Arts Education Program (AAE)—Arts in Education National Program (AENP) Grants, Catalog of Federal Domestic Assistance (CFDA) number 84.351F.

DATES:

Applications Available: May 7, 2018.

Deadline for Notice of Intent to Apply: June 6, 2018.

Deadline for Transmittal of Applications: July 6, 2018.

Deadline for Intergovernmental Review: September 4, 2018.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

FOR FURTHER INFORMATION CONTACT: Asheley McBride, U.S. Department of Education, 400 Maryland Avenue SW, Room 4W240, Washington, DC 20202–5950. Telephone: (202) 453–6398. Email: *Asheley.McBride@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:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The AENP—part of the Assistance for Arts Education (AAE) program—is authorized under Title IV, part F, subpart 4 of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA).[1] In general, the purpose of the AAE program is to promote arts (as defined in this notice) education for students, including disadvantaged students and students who are children with disabilities (as defined in this notice). Specifically, the AENP supports national-level (as defined in this notice), high-quality arts education projects and services for children and youth, with special emphasis on serving children from low-income families (as defined in this notice) and children with disabilities through community and national outreach activities that strengthen and expand partnerships among schools, local educational agencies, communities, or centers for the arts, including national centers for the arts.

Background: Since 2001, the Department has invested over $300 million in arts education and arts integration (as defined in this notice). The AENP, under its new authorization, will continue to build on the Department's contributions to the arts. The new authorization of the AENP emphasizes projects that support community and national outreach activities that strengthen and expand partnerships among schools, local educational agencies (LEAs), communities, or centers for the arts, including national centers for the arts.

In addition, under the new authorization, the AENP will continue to support activities and services that were previously funded through this program including: developing and updating standards-aligned, arts-based and arts-integrated curriculum and programming; professional development for educators, including special educators and arts educators; dissemination of instructional materials and online resources; and other high-quality projects for children and youth, with special emphasis on serving children from low-income families and children with disabilities.

Priorities: This notice includes one absolute priority. We are establishing this priority for the FY 2018 grant competition and any subsequent years in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priority: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

One or more high-quality arts education projects that (1) support community and national outreach activities that strengthen and expand partnerships among schools, local educational agencies (LEAs), communities, or centers for the arts, including national centers for the arts; (2) are designed to implement, or expand, initiatives in arts education and arts integration; and (3) have a special emphasis on serving children from low-income families and children with disabilities. To meet part 3 of this priority, applicants must submit supporting data identifying the population of students that meet the definition of ''child from a low-income family'' and the population of students that meet the definition of ''child with a disability.'' The supporting data for a child from a low-income family will reflect the data used by the LEA referred to in the definition of ''child from a low-income family'' in this notice.

Definitions: We are establishing the definitions of ''arts,'' ''arts educator,'' ''arts integration,'' and ''child from a low-income family'' for the FY 2018 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA. The definition of ''child with a disability'' is from section 8101 of the ESEA (20 U.S.C. 7801). The definitions of ''demonstrates a rationale,'' ''experimental study,'' ''logic model,'' ''project component,'' ''national level,'' ''promising evidence,'' ''quasi-experimental design study,'' ''relevant outcome'' and ''What Works Clearinghouse Handbook (WWC Handbook)'' are from 34 CFR 77.1(c).

Arts means music, dance, theater, media arts, and visual arts, including folk arts.

Arts educator means a teacher or other instructional staffer who works in music, dance, theater, media arts, or visual arts, including folk arts.

Arts integration means (1) strengthening the use of high-quality arts instruction in other academic/content areas, and (2) strengthening the place of the arts as a part of a well-rounded education.

Child from a low-income family means a child who is determined by a state or local educational agency to be a child, in pre-kindergarten through grade 12 (a) who is in poverty counted in the most recent census data, (b) who is eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act, (c) whose family is receiving assistance under the State program funded under part A of title IV of the Social Security Act, (d) who is eligible to receive medical assistance under the Medicaid program, or (e) a composite of such indicators.

Child with a disability means—

(a) A child (i) with intellectual disabilities, hearing impairments (including deafness), speech or language impairments, visual impairments (including blindness), serious emotional disturbance (referred to as ''emotional disturbance''), orthopedic impairments, autism, traumatic brain injury, other health impairments, or specific learning disabilities; and (ii) who, by reason thereof, needs special education and related services.

[1] Unless otherwise indicated, all references to the ESEA are to the ESEA, as amended by the ESSA.

(b) For a child aged 3 through 9 (or any subset of that age range, including ages 3 through 5), may, at the discretion of the State and the local educational agency, include a child (i) experiencing developmental delays, as defined by the State and as measured by appropriate diagnostic instruments and procedures, in one or more of the following areas: physical development; cognitive development; communication development; social or emotional development; or adaptive development; and (ii) who, by reason thereof, needs special education and related services.

Demonstrates a rationale means a key project component (as defined in this notice) included in the project's logic model (as defined in this notice) is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes (as defined in this notice).

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook (as defined in this notice):

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

National level describes the level of scope or effectiveness of a process, product, strategy, or practice that is able to be effective in a wide variety of communities, including rural and urban areas, as well as with different groups (*e.g.,* economically disadvantaged, racial and ethnic groups, migrant populations, individuals with disabilities, English learners, and individuals of each gender).

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

What Works Clearinghouse Handbook (WWC Handbook) means the standards and procedures set forth in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, definitions and selection criteria. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 4642 of the ESSA (20 U.S.C. 7292) and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priority, definitions, and one of the selection criteria, under section 437(d)(1) of GEPA. This priority, these definitions and this selection criterion will apply to the FY 2018 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 7291–7292.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.
Estimated Available Funds: $8,000,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months (subject to availability of funds).

III. Eligibility Information

1. *Eligible Applicants:* Eligible national nonprofit organizations. ''Eligible national nonprofit organization'' means an organization of national scope that—

(A) Is supported by staff, which may include volunteers, or affiliates at the State and local levels; and

(B) Demonstrates effectiveness or high-quality plans for addressing arts education activities for disadvantaged students or students who are children with disabilities.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This program involves supplement-not-supplant funding requirements. In accordance with section 4642(b)(2)of the ESEA, funds made available under this subpart shall be used only to supplement, and not to supplant, any other assistance or funds made available from non-Federal sources for the activities assisted under this subpart.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Coordination Requirement:* In accordance with section 4642(b)(1) of the ESEA, grantees are required to coordinate, to the extent practicable, each project or program carried out with such assistance with appropriate activities of public or private cultural agencies, institutions, and organizations, including museums, arts education associations, libraries, and theaters.

IV. Application and Submission Information

1. *Application Submission Instructions:* For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the AENP, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

We plan on posting the project narrative section of funded AENP applications on the Department's website. Accordingly, you may wish to request confidentiality of business information. Identifying proprietary information in the submitted application will help facilitate this public disclosure process.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the absolute priority and the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* We will be able to develop a more efficient process for reviewing grant applications if we know the approximate number of applicants that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify us of the applicant's intent to submit an application for funding by sending a short email message. This email should only indicate the applicant organization's name and address. Please send this email notification to *Asheley.McBride@ed.gov* with ''Intent to Apply'' in the email subject line. Applicants that do not provide this email notification may still apply for funding.

7. *Informational Webinar:* The AENP staff intends to hold a webinar designed to provide technical assistance to all interested grant applicants. Detailed information regarding this webinar will be provided on the AENP web page at: *https://innovation.ed.gov/what-we-do/arts/arts-in-education-national-program/.*

V. Application Review Information

1. *Selection Criteria:* We are establishing selection criterion (b) under the *Quality of the project design* for the FY 2018 grant competition and any subsequent years in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1). Selection criterion (a) under the *Quality of the project design* is from section 4642(a)(1)(C) of the ESEA. The rest of the selection criteria for this competition are from 34 CFR 75.210.

The points assigned to each criterion are indicated in the parentheses next to the criterion. An applicant may earn up to a total of 100 points based on the selection criteria for the application.

The selection criteria are as follows:

(1) *Significance* (20 points).

The Secretary reviews each application to determine—

(a) The national significance of the proposed project.

(b) The extent to which the results of the proposed project are to be disseminated in ways that will enable others to use the information or strategies.

(c) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(2) *Quality of the project design* (35 points). The Secretary reviews each application to determine the extent to which—

(a) The proposed project will provide community and national outreach activities that strengthen and expand partnerships among schools, local educational agencies, communities, or centers for the arts, including national centers for the arts.

(b) The proposed project is appropriate to, and will successfully address, the arts education needs of pre-kindergarten-through-grade-12 children and youth, with special emphasis on serving children from low-income families and children with disabilities;

(c) The proposed project will integrate with or build on similar or related efforts to improve relevant outcomes (as defined in this notice), using existing funding streams from other programs or policies supported by community, State, and Federal resources.

(d) The proposed project demonstrates a rationale (as defined in this notice).

Note: The Secretary encourages applicants to consider measures and targets tied to their grant activities. The measures and targets should be sufficient to gauge the progress throughout the grant period, and show results by the end of the grant period. For technical assistance in developing effective measures and targets, applicants are encouraged to review information provided by the Department's Regional Educational Laboratories (RELs). The RELs seek to build the capacity of States and school districts to incorporate data and research into education decision making. Each REL provides research support and technical assistance to its region but makes learning opportunities available to educators everywhere. For example, the REL Northeast and Islands has created the following resources on logic models: *http://relpacific.mcrel.org/resources/elm-app/; https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014025.pdf; https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014007.pdf;* and *https://ies.ed.gov/ncee/edlabs/regions/northeast/pdf/REL_2015057.pdf.*

(3) *Quality of project services* (25 points).

In determining the quality of the services to be provided by the proposed project, the Secretary considers the following factors:

(a) The likely impact of the services to be provided by the proposed project on the intended recipients of those services.

(b) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(c) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

(4) *Quality of the project evaluation* (20 points).

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the project evaluation, the Secretary considers the following factors:

(a) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(b) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(c) The extent to which the methods of evaluation will, if well implemented, produce promising evidence (as defined in this notice) about the project's effectiveness.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other

requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* Under the Government Performance and Results Act (GPRA), we have established four performance measures to assess the effectiveness of this program. Projects funded under this competition will be expected to collect and report to the Department data related to these measures. Applicants should, but are not required to, discuss in the application narrative how they propose to collect these data. The four GPRA performance measures are: (1) The total number of students who participate in arts education sponsored by the grantee; (2) the number of teachers participating in the grantee's program who receive professional development; (3) the total number of low-income students who participate in arts education sponsored by the grantee; and (4) the total number of children with disabilities who participate in arts education sponsored by the grantee.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package 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 via the Federal Digital System at: *www.gpo.gov/fdsys.* 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.

Dated: May 2, 2018.

Margo Anderson,

Acting Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2018–09669 Filed 5–4–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Update on Reimbursement for Costs of Remedial Action at Uranium and Thorium Processing Sites

AGENCY: Department of Energy.

ACTION: Notice of the Title X claims during fiscal year (FY) 2018.

SUMMARY: This Notice announces the Department of Energy's (DOE) acceptance of claims in FY 2018 from eligible uranium and thorium processing site licensees for reimbursement under Title X of the Energy Policy Act of 1992. The FY 2019 Department of Energy Office of Environmental Management's Congressional Budget Request included $30 million for the Title X Program.

DATES: The closing date for the submission of FY 2018 Title X claims is September 14, 2018. The claims will be processed for payment together with any eligible unpaid approved claim balances from prior years, based on the availability of funds from congressional appropriations. If the total approved claim amounts exceed the available funding, the approved claim amounts will be reimbursed on a prorated basis. All reimbursements are subject to the availability of funds from congressional appropriations.

ADDRESSES: Claims should be forwarded by certified or registered mail, return receipt requested, to U.S. Department of Energy, Office of Legacy Management, Attn: Mark Kautsky, Lead for Review of Title X Reimbursement of Claims, U.S. Department of Energy, Office of Legacy Management, 2597 Legacy Way, Grand Junction, Colorado 81503. Two copies of the claim should be included with each submission.

FOR FURTHER INFORMATION CONTACT: Jaffet Ferrer-Torres, Title X Program Lead and Coordinator, at (202) 586–0730, of the U.S. Department of Energy, Office of Environmental Management, Office of Waste Disposal.

SUPPLEMENTARY INFORMATION: DOE published a final rule under 10 CFR part 765 in the **Federal Register** on May 23, 1994, (59 FR 26714) to carry out the

requirements of Title X of the Energy Policy Act of 1992 (sections 1001–1004 of Public Law 102–486, 42 U.S.C. 2296a *et seq.*) and to establish the procedures for eligible licensees to submit claims for reimbursement. DOE amended the final rule on June 3, 2003, (68 FR 32955) to adopt several technical and administrative amendments (*e.g.,* statutory increases in the reimbursement ceilings). Title X requires DOE to reimburse eligible uranium and thorium licensees for certain costs of decontamination, decommissioning, reclamation, and other remedial action incurred by licensees at uranium and thorium processing sites to remediate byproduct material generated resulting from the sales to the United States Government. To be reimbursable, costs of remedial action must be for work that is necessary to comply with applicable requirements of the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 *et seq.*) or, where appropriate, with requirements established by a State pursuant to a discontinuance agreement under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021). Claims for reimbursement must be supported by reasonable documentation as determined by DOE in accordance with 10 CFR part 765. Funds for reimbursement will be provided from the Uranium Enrichment Decontamination and Decommissioning Fund established at the Department of Treasury pursuant to section 1801 of the Atomic Energy Act of 1954 (42 U.S.C. 2297g). Payment or obligation of funds shall be subject to the requirements of the Anti-Deficiency Act (31 U.S.C. 1341).

Authority: Section 1001–1004 of Public Law 102–486, 106 Stat. 2776 (42 U.S.C. 2296a *et seq.*).

Issued in Washington, DC, on May 1, 2018.

Jaffet Ferrer-Torres,

Title X Program Lead and Coordinator, Office of Waste Disposal, Office of Environmental Management.

[FR Doc. 2018–09621 Filed 5–4–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1471–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization: ACT Commodities, Inc.

This is a supplemental notice in the above-referenced proceeding of ACT Commodities, Inc.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 21, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–09616 Filed 5–4–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP18–749–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Service Agreement—Mercuria LPS 5/1/2018 to be effective 5/1/2018.
Filed Date: 4/30/18.
Accession Number: 20180430–5022.
Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–750–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Remove Expired Agmts from Tariff eff 5/1/2018 to be effective 5/1/2018.
Filed Date: 4/30/18.
Accession Number: 20180430–5081.
Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–751–000.
Applicants: Cheyenne Plains Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Fuel and EPC Update Filing to be effective 6/1/2018.
Filed Date: 4/30/18.
Accession Number: 20180430–5083.
Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–752–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco Redes May 18) to be effective 5/1/2018.
Filed Date: 4/30/18.
Accession Number: 20180430–5102.
Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–753–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Amendment to Negotiated Rate Agreememt—DTE Energy to be effective 5/1/2018.
Filed Date: 4/30/18.
Accession Number: 20180430–5104.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–754–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: Quarterly FL&U Update to be effective 6/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5173.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–755–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (Centennial May 18) to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5218.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–756–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Filing (MRC Permian May 18) to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5227.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–757–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—May 2018 to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5238.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–758–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) Rate Filing: 2018 May Negotiated Rate Agreements to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5285.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–759–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2018–04–30 E2W 5 Ks to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5339.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–760–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates for NJR ES effective 5/1/2018 to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5348.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–761–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2018–04–30 CP to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5357.

Comments Due: 5 p.m. ET 5/14/18.

Docket Numbers: RP18–762–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Clarifications to Request for Services and Pro Formas Filing to be effective 6/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5350.

Comments Due: 5 p.m. ET 5/14/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–09619 Filed 5–4–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. PR17–60–001; PR17–60–002]

Notice of Technical Conference: Atmos Pipeline—Texas

Take notice that an informal technical conference concerning the above-captioned proceedings will be convened by phone on May 23, 2018, at 2:00 p.m. (EDT). The purpose of the teleconference will be to discuss comments filed in the proceeding.

All interested parties are invited to participate by phone. Please email Deirdra Archie at *deirdra.archie@ferc.gov* or call (202) 502–6819 by Tuesday, May 22, 2018, to RSVP and to receive specific instructions on how to participate.

Dated: May 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–09617 Filed 5–4–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1470–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization: Pine River Wind Energy LLC

This is a supplemental notice in the above-referenced proceeding of Pine River Wind Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 21, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the

Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–09615 Filed 5–4–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *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. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited:		
1. P–10482–000	4–17–2018	Ross L Hadden.
2. CP15–554–000	4–26–2018	Anne S. Bryan.
3. CP17–101–000	4–26–2018	Durand Carson.
4. CP17–101–000	4–26–2018	Jason A. Sneider.
5. CP17–101–000	4–26–2018	Brooke Taylor.
6. CP17–101–000	4–26–2018	Steve Grimes.
7. CP17–101–000	4–26–2018	Peter Butler.
8. CP17–101–000	4–26–2018	Raynold W. Wilson Jr.
9. CP17–101–000	4–26–2018	Anthony Sasso.
10. CP17–101–000	4–26–2018	Phillip McCann.
11. CP17–101–000	4–26–2018	Richard Niederberger.
12. CP17–101–000	4–26–2018	Robert Slick.
Exempt:		
1. P–2100–000	4–20–2018	U.S. House Representative Doug LaMalfa.
2. P–2100–000	4–20–2018	U.S. Senator Dianne Feinstein.
3. CP16–17–000	4–24–2018	Village of Warwick, New York.
4. CP15–88–000; CP15–88–001	4–26–2018	City of Richmond, Kentucky; Mayor Jim Barnes.
5. CP17–101–000	4–27–2018	350Brooklyn.

Dated: May 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–09618 Filed 5–4–18; 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: EG18–79–000.

Applicants: Sholes Wind Energy, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Sholes Wind Energy, LLC.

Filed Date: 5/1/18.

Accession Number: 20180501–5161.

Comments Due: 5 p.m. ET 5/22/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2390–003; ER10–2394–005; ER10–2395–005 ER10–2422–005; ER11–3642–018; ER12–1562–005 ER12–1563–005.

Applicants: Bicent (California) Malburg LLC, BIV Generation Company, L.L.C., Cayuga Operating Company, LLC, Colorado Power Partners, Rocky Mountain Power, LLC, Tanner Street Generation, LLC, Somerset Operating Company, LLC.

Description: Notice of Non-Material Change in Status of Bicent (California) Malburg LLC, et. al.

Filed Date: 4/30/18.

Accession Number: 20180430–5461.

Comments Due: 5 p.m. ET 5/21/18.

Docket Numbers: ER18–1184–000; ER18–1183–000.

Applicants: Delta Solar Power II, LLC, Delta Solar Power I, LLC.

Description: Supplement to March 22, 2018 Delta Solar Power I, LLC and Delta Solar Power II, LLC tariff filings.

Filed Date: 4/27/18.

Accession Number: 20180427–5308.

Comments Due: 5 p.m. ET 5/18/18.

Docket Numbers: ER18–1480–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: First Revised ISA, SA No. 2133, Queue No. AC1–140 to be effective 3/29/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5301.

Comments Due: 5 p.m. ET 5/21/18.

Docket Numbers: ER18–1481–000.

Applicants: Duke Energy Florida, LLC.

Description: § 205(d) Rate Filing: DEF IA Annual Cost Factor Update (2018) to be effective 5/1/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5328.

Comments Due: 5 p.m. ET 5/21/18.

Docket Numbers: ER18–1482–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Q1 2018 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 3/31/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5343.

Comments Due: 5 p.m. ET 5/21/18.

Docket Numbers: ER18–1483–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: 1st Quarter 2018 Revisions to OA, Sch. 12 and RAA, Sch. 17 Member Lists to be effective 3/31/2018.

Filed Date: 4/30/18.

Accession Number: 20180430–5351.

Comments Due: 5 p.m. ET 5/21/18.

Docket Numbers: ER18–1485–000.

Applicants: New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: May 2018 Membership Filing to be effective 4/1/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5009.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1486–000.

Applicants: AEP Ohio Transmission Company, Inc.

Description: § 205(d) Rate Filing: OHTCo-Buckeye Cardinal SA to be effective 6/30/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5010.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1487–000.

Applicants: Southwestern Electric Power Company.

Description: § 205(d) Rate Filing: Rayburn Revised PSA to be effective 5/31/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5016.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1488–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEP TX-Texas-New Mexico Power IA 3rd Amend & Restated to be effective 4/16/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5273.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1489–000.

Applicants: SP Cimarron I, LLC.

Description: § 205(d) Rate Filing: Market-Based Rate Tariff Amendment to Reflect Name Change to be effective 5/2/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5275.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1490–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEP TX-Patriot Wind Farm IA 4th Amend & Restated to be effective 4/13/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5278.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1491–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEPTX-Las Majadas Wind Farm Interconnection Agreement to be effective 4/13/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5280.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1492–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: First Revised ISA, SA No. 4627; Queue No. AA1–076/AC1–108 to be effective 3/30/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5288.

Comments Due: 5 p.m. ET 5/22/18.

Docket Numbers: ER18–1493–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2018–05–01_Order 825 Price Formation True-up Filing to be effective 7/1/2018.

Filed Date: 5/1/18.

Accession Number: 20180501–5293.

Comments Due: 5 p.m. ET 5/22/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–09614 Filed 5–4–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Olmsted Powerplant Replacement Project-Rate Order No. WAPA–177

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of order concerning final rate for the Olmsted Powerplant Replacement Project.

SUMMARY: The Deputy Secretary of Energy confirmed and approved Rate Order No. WAPA–177 and Rate Schedule F–1, placing the formula rate for the Western Area Power Administration (WAPA) Olmsted Powerplant Replacement Project (Olmsted) into effect on an interim basis (Provisional Formula Rate).

DATES: The Provisional Formula Rate Schedule Olmsted F–1 is effective on the first day of the first, full billing period beginning on or after June 6, 2018, and will remain in effect through May 6, 2023, pending confirmation and

approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Mr. Brent Osiek, Power Marketing Manager, Colorado River Storage Project Management Center, Western Area Power Administration, 299 South Main Street, Suite 200, Salt Lake City, UT 84111, telephone (801) 524–5495, or Mr. Thomas Hackett, Rates Manager, Colorado River Storage Project Management Center, Western Area Power Administration, 299 South Main Street, Suite 200, Salt Lake City, UT 84111, telephone (801) 524–5503, email *hackett@wapa.gov.*

SUPPLEMENTARY INFORMATION: Olmsted is located at the mouth of Provo Canyon in northern Utah and is a part of the Central Utah Project, a participating project of the Colorado River Storage Project (CRSP). In order to secure water rights necessary for the Central Utah Project, the United States Department of the Interior initiated condemnation proceedings in 1987 to acquire the Olmsted facility from Utah Power and Light (now PacifiCorp). Under the terms of the condemnation settlement agreement, PacifiCorp was allowed to operate the Olmsted facility until September 2015. Upon expiration of the settlement agreement, replacement construction began due to the age and condition of the existing generating plant. The Project is scheduled to begin commercial service on August 1, 2018.

Olmsted is a ''take all, pay all'' project; *i.e.,* the annual revenue requirement is not dependent upon the amount of energy available each year. Customers with an allocation, as determined by the marketing plan process, will receive a proportional share of the energy and will annually pay a proportional share of the operation, maintenance, and replacement (OM&R) expenses in 12 monthly installments. This Notice establishes the initial formula rate for Olmsted under Rate Schedule F–1. The initial formula rate is as follows: Annual Revenue Requirement = Projected OM&R Costs + Projected Interest + Projected Principal Payments ± True-Up Adjustment.

Legal Authority

By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of WAPA; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to FERC. Federal rules (10 CFR part 903) govern DOE procedures for public participation in power rate adjustments.

Under Delegation Order Nos. 00–037.00B and 00–001.00F and in compliance with 10 CFR part 903 and 18 CFR part 300, I hereby confirm, approve, and place Rate Order No. WAPA–177, Olmsted Powerplant Replacement Project, into effect on an interim basis. The new Rate Schedule F–1 will be submitted to FERC for confirmation and approval on a final basis.

Dated: April 30, 2018.

Dan Brouillette,

Deputy Secretary of Energy.

DEPARTMENT OF ENERGY DEPUTY SECRETARY

In the matter of: Western Area Power Administration, Rate Order for the Olmsted Powerplant Replacement Project.

Rate Order No. WAPA–177

ORDER CONFIRMING, APPROVING, AND PLACING THE OLMSTED POWERPLANT REPLACEMENT PROJECT FORMULA RATE INTO EFFECT ON AN INTERIM BASIS

The formula rate for the Olmsted Powerplant Replacement Project (Olmsted) set forth in this order is established in accordance with section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Act of 1939 (43 U.S.C. 485h(c)); and other acts that specifically apply to the projects involved.

By Delegation Order No. 00–037.00B, effective November 19, 2016, the Secretary of Energy delegated: (1) The authority to develop power and transmission rates to the Administrator of Western Area Power Administration (WAPA); (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). Federal rules (10 CFR part 903) govern DOE procedures for public participation in power rate adjustments.

Acronyms, Terms, and Definitions

As used in this Rate Order, the following acronyms, terms, and definitions apply:

Allocation: A portion of Olmsted generation assigned a particular customer.

CRSP Act Section 5(c): All revenues collected in connection with the operation of the Colorado River Storage Project and participating projects shall be credited to the Basin Fund, and shall be available, without further appropriation, for (1) defraying the costs of operation, maintenance, and replacements of, and emergency expenditures for, all facilities of the Colorado River Storage Project and participating projects, within such separate limitations as may be included in annual appropriation acts; *lrovided, that* with respect to each participating projects, such costs shall be paid from revenues received from each such project; (2) payment as required by subsection (d) of this section; and (3) payment as required by subsection (e) of this section. Revenues credited to the Basin Fund shall not be available for appropriation for construction of the units and participating projects authorized by or pursuant to this Act.

Customer: An entity with a contract that is receiving an allocation of the Olmsted generation.

DOE Order RA 6120.2: An order outlining power marketing administration financial reporting and ratemaking procedures.

Energy: Measured in terms of the work it is capable of doing over a period of time. Electric energy is expressed in kilowatt-hours.

Environmental Documentation: Includes the Olmsted Hydroelectric Powerplant Replacement Project Final Environmental Assessment, Finding of No Significant Impact (FONSI) and the Memorandum of Agreement among the CUWCD, Interior, and the Utah State Historical Preservation Officer regarding the Olmsted Hydroelectric Powerplant Replacement Project.

FY: Fiscal year; October 1 to September 30.

Funding Agreement: Parties to the agreement are United States Department of the Interior—Bureau of Reclamation (Reclamation), United States Department of the Interior—Central Utah Project Completion Act Office, and Central Utah Water Conservancy District (District). The agreement describes the sources of funding for the project including non-Federal contributed

funds and provides for the transfer of funds from Reclamation to the District.

Implementation Agreement: Memorandum of Understanding among the United States Department of the Interior—Bureau of Reclamation (Reclamation), United States Department of the Interior—Central Utah Project Completion Act Office, Central Utah Water Conservancy District, and Western Area Power Administration. It describes the proposed project and responsibilities of the parties.

Installment: Annual Revenue Requirement billed to customers in 12 equal monthly payments.

M&I: Municipal and Industrial water supplies and uses.

MW: Megawatt—the electrical unit of capacity that equals 1 million watts or 1,000 kilowatts.

O&M: Operation and Maintenance.

OM&R: Operation, Maintenance, and Replacements.

Power: Rate at which electric energy is transferred. Electric power is measured by capacity and is commonly expressed in megawatts.

Provisional Formula Rate: A formula rate confirmed, approved, and placed into effect on an interim basis by the Deputy Secretary of Energy.

PRS: Power Repayment Study.

Revenue Requirement: The revenue required by the PRS to recover annual expenses (such as O&M, transmission service expenses, interest, and deferred expenses) and repay Federal investments and other assigned costs.

Effective Date

The Provisional Olmsted Formula Rate Schedule F–1 will take effect on the first day of the first, full billing period beginning on or after June 6, 2018, and will remain in effect through May 6, 2023, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

WAPA followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR part 903, in developing this rate and schedule. The steps WAPA took to involve interested parties in the rate process were:

1. A **Federal Register** notice (FRN), published on October 12, 2017 (82 FR 47506) (Proposal FRN), announced the proposed rate for Olmsted and began the 90-day public consultation and comment period.

2. On October 17, 2017, WAPA's CRSP MC emailed an announcement of the November 17, 2017, public information and public comment forums to power customers of the CRSP MC, CRSP transmission customers, and interested parties, along with the Rate Brochure, which contained a copy of the published FRN proposal. This information was also posted to website: *https://www.wapa.gov/regions/CRSP/rates/Pages/rates.aspx.*

3. On November 17, 2017, at 10 a.m. (MST), WAPA held a public information forum at the CRSP MC, 299 South Main Street, Suite 200, Salt Lake City, Utah. WAPA provided information about the proposed Olmsted formula rate. WAPA also answered questions and gave notice that more information was available in the customer rate brochure and on the website located at *https://www.wapa.gov/regions/CRSP/rates/Pages/rate-order-177.aspx.*

4. On November 17, 2017, directly following the public information forum, WAPA held a public comment forum at the same location to provide an opportunity for customers and other interested parties to comment for the record. Three verbal comments were received at this forum.

5. WAPA posted critical dates, customer letters, presentations, FRNs, customer brochure, and other information about this rate process at the website located at: *https://www.wapa.gov/regions/CRSP/rates/Pages/rate-order-177.aspx.* Updates to the site were posted as follows:

October 17, 2017: Olmsted Customer Brochure, Customer Letter for Proposed FRN, and the Published FRN—Olmsted Proposed Rates.

November 15, 2017: Updated Customer Brochure with updated Table 1 (pg. 7) and Schedule (pg. 16).

November 17, 2017: Public Information Forum Presentation.

December 4, 2017: Implementation Agreement, Memorandum of Concurrence, Funding Agreement, Table A & Olmsted Costs.

December 6, 2017: Public Information Forum and Public Comment Forum transcripts.

January 25, 2018: Letter Agreement No: 92–SLC–0208, Olmsted Final Environmental Assessment, comment letters received during the public comment period.

6. During the 90-day consultation and comment period that ended on January 10, 2018, WAPA received three verbal comments and five comment letters. The comments and WAPA's responses are addressed below. All comments have been considered in the preparation of this Rate Order.

Three representatives from the following organizations made verbal comments:

Central Utah Water Conservancy District, Utah
Colorado River Energy Distributors Association, Arizona
Utah Associated Municipal Power Systems, Utah

Five representatives from the following organizations provided written comments:

Central Utah Project Completion Act Office, Utah
Central Utah Water Conservancy District, Utah
Colorado River Energy Distributors Association, Arizona
Utah Associated Municipal Power Systems, Utah
Utah Municipal Power Agency

Project Description

Olmsted is located at the mouth of Provo Canyon in northern Utah and is a part of the Central Utah Project, a participating project of the Colorado River Storage Project (CRSP). In order to secure water rights necessary for the Central Utah Project, the United States Department of the Interior initiated condemnation proceedings in 1987 to acquire the Olmsted facility from Utah Power and Light (now PacifiCorp). Under the terms of the condemnation settlement agreement, PacifiCorp was allowed to operate the Olmsted facility until September 2015. Upon expiration of the settlement agreement, replacement construction began due to the age and condition of the existing generating plant. Olmsted is scheduled to begin commercial service on August 1, 2018.

Olmsted is a ''take all, pay all'' project; *i.e.,* the annual revenue requirement is not dependent on the amount of energy available each year. Customers with an allocation, as determined by the marketing plan process, will receive a proportional share of the energy and will annually pay a share of the operation, maintenance, and replacement (OM&R) expenses in 12 monthly installments.

Power Repayment Study—Formula Rate

Repayment criteria are based on applicable laws and legislation as well as policies including DOE Order RA 6120.2. To meet the Cost Recovery Criteria outlined in DOE Order RA 6120.2, WAPA will prepare a Power Repayment Study (PRS) each FY to determine if revenues will be sufficient to repay, within the required time, all costs assigned to Olmsted.

Under the provisional rate methodology, the formula rate for Olmsted is designed to recover an annual revenue requirement that includes power investment repayment,

interest, O&M, and other expenses within the allowable period. The annual revenue requirement is proportionally distributed among all customers that have an allocated portion of Olmsted energy production. Annual OM&R obligations and related costs for Olmsted will be paid by designated revenues deposited in the Basin Fund, pursuant to the authority of Section 5(c) of the CRSP Act, attributable to the Central Utah Project including the OM&R costs of Olmsted Facilities; OM&R costs for the Olmsted Facilities located upstream of Olmsted Facilities; and costs associated with preservation of the historic power house that will be preserved and maintained as a museum as agreed with the Utah Division of State History (State Historic Preservation Office) as part of the National Environmental Policy Act (NEPA) process associated with Olmsted. The actual and projected investment and OM&R costs requiring repayment are shown in Table 1.

TABLE 1—PROJECTED INVESTMENT AND OM&R COSTS REIMBURSABLE BY POWER CUSTOMERS

FY	2018	2019	2020	2021	2022	2023	2024
Capitalized							
Generation/SCADA	.....	$5,815,169	.....	.....	.....	.....	.....
Historic Preservation	.....	.....	$500,000	$500,000	$500,000	.....	.....
Total Capitalized	.....	5,815,169	500,000	500,000	500,000	.....	.....
Expensed							
Historic Preservation	$10,000	10,000	20,000	20,000	20,000	$50,000	$30,000
Powerplant	0	100,000	175,000	180,250	185,658	191,227	196,964
Intake & Pipeline	0	39,054	277,724	352,976	206,070	177,754	342,087
USBR O&M	10,000	27,500	10,000	10,000	27,500	10,000	10,000
WAPA O&M	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Wheeling Charge	50,000	200,000	200,000	200,000	200,000	200,000	200,000
Total O&M	80,000	386,554	692,724	773,226	649,227	638,981	789,051

WAPA will calculate the annual revenue requirement based on 2 years of data. The calculation includes the projected costs of the rate installment year (future FY) and an adjustment from the last historic FY. Annual revenues pay the annual amortized portion of the United States' investment in Olmsted with interest and the associated OM&R. The adjustment is the surplus or deficit that occurs in the last historic year when actual costs and repayment obligations are subtracted from actual revenues. This surplus or deficit is combined with the projected rate installment year costs to arrive at the revenue requirement. To date, all investments are accounted for as Construction in Progress (CIP) costs and have not been transferred to plant accounts for capitalization. Once transferred, a straight-line amortization schedule will be calculated for repayment. Historical financial data are only available through FY 2016, and projections are based on the FY 2019 Reclamation and WAPA work plans received in April 2017, as indicated in Table 1.

WAPA will provide Olmsted power customers with the initial installment information at least 30 days prior to initiation of service. The FY 2018 annual installment will include all projected FY 2018 OM&R costs requiring repayment through FY 2018. The FY 2018 installment amount will be divided by the number of months of service, which is anticipated to be 3 months. Thereafter, the annual installment amount, billed in 12 monthly payments, will be established in advance by WAPA and submitted to Olmsted power customers on or before August 31 prior to the new FY. The FY 2019 annual installment will include the projected FY 2019 OM&R costs in addition to amortized payments on capital investments plus interest. The FY 2020 annual installment will be similar to FY 2019; however, it will include the FY 2018 final financial data and any True-Up between the FY 2018 projected costs and the actual FY 2018 costs.

Existing and Provisional Formula Rates

There is no existing rate for the Project. This Notice establishes the initial formula rate for Olmsted under Rate Schedule F–1. The initial formula rate is as follows: Annual Revenue Requirement = Projected OM&R Costs + Projected Interest + Projected Principal Payments ± True-Up Adjustment.

Certification of Rates

WAPA's Administrator certified that the Provisional Formula Rate for the Olmsted Powerplant Replacement Project under Rate Schedule F–1 results in the lowest possible rate consistent with sound business principles.

Basis for Rate Development

The Provisional Formula Rate under Rate Schedule F–1 will provide sufficient revenue to pay all annual costs, including interest expenses, and repay investments within the allowable periods.

Comments

WAPA received three verbal comments and five comment letters during the public consultation and comment period. The comments expressed have been paraphrased, where appropriate, without compromising the meaning of the comments. Direct quotes from comment letters are used for clarity where necessary.

Comment: One commenter stated they are contributing up to 15 million of local tax revenues to support this project and are counting on power revenues to reimburse O&M expenses.

Response: WAPA's rate captures the yearly O&M expenses related to power, and those expenses will be included in the rate as will the repayment of funds from Section 5(c) of the CRSP Act contributed to the project. WAPA acknowledges that the cost of the Olmsted Project is being supported by local tax dollars as well from other funding sources.

Comment: Commenter appreciated the information provided by WAPA during the public information and

comment forum as well as on the website.

Response: WAPA will continue its efforts to provide transparency throughout the process.

Comment: Commenter supports the proposed rate formula, which is consistent with the rate structure of the Provo River Project, including the true-up provisions to ensure only actual costs are attributed to the project and billed to customers.

Response: WAPA acknowledges the comment.

Comment: Commenter requested to be kept apprised of any revisions to Table A of the implementation agreement and to be notified and included in the annual customer/stakeholder meetings due to their relationship with Reclamation and WAPA. Commenter suggested that all attendees at the forum(s) be notified of the availability of updated and additional information.

Response: A list of updates is posted in the ''Public Notice and Comment'' section of this document. WAPA sends out notifications when uploading data to the website so all participants have equitable access to the same information. Olmsted customers will be invited to annual rate meetings to discuss yearly repayment expenses as well as planned O&M costs.

Comment: A commenter stated given the successful customer/agency partnership model of Agreement No. 92–SLC–0208, WAPA, Reclamation, and CUWCD should consider a similar process/agreement with the ultimate allottees of the Olmsted Project as a complement to Olmsted Implementation Agreement (Contract WS15–100).

Response: While this comment is not within the scope of this rate process, WAPA has posted a copy of Agreement No. 92–SLC–0208 to the Olmsted Rate website located at *https://www.wapa.gov/regions/CRSP/rates/Pages/rate-order-177.aspx* for informational purposes and for consideration in future discussions about whether a similar partnership agreement would be appropriate.

Comment: Commenter asked whether the WAPA O&M rate component includes appropriate overhead/loading costs to ensure there is no subsidy between other WAPA projects and the Olmsted Project.

Response: In addition to power marketing labor costs, the work plan includes depreciation expense (ADEPR), and applies both a headquarters' and regional Administrative & General Expense (AGE) overhead burden similar to all CRSP MC projects.

Comment: Commenter questioned the difference between the cost table in the Proposal FRN and the one presented at the public information forum. Additionally, there was a request to provide additional delineation in the Olmsted O&M table including which costs associated with the historic preservation of the Olmsted Powerhouse would be capitalized versus expensed.

Response: WAPA used the cost table from the Implementation Agreement in the Proposal FRN. WAPA subsequently received an update from CUWCD with additional construction costs that increased the total estimated project by 12 million and that cost table was introduced at the public information forum. However, of the differences noted between the tables, only the 300,000 increase in CRSP Act Section 5(c) funding is reimbursable by power customers. The capitalized and expensed costs for historic preservation are segregated in Table 1.

Comment: A commenter stated, that: ''The annual revenues projected from the power revenue for each annual installment, adjusted as provided in the rate order, must be sufficient to reimburse the annual O&M expenses for operation of the Olmsted Project and must not be decreased on account of other revenue also deposited into the Basin Fund. The CUWCD anticipates participating in annual customer meetings and coordinating, more often outside those annual customer meetings, with the CUPCA office of the Department of Interior, Reclamation Power office and WAPA, to provide budget work plans and capital improvement and rehabilitation plans that can be used for calculating the most accurate annual installments by WAPA.''

Response: Revenues received from the sale of Olmsted power will be deposited in the Basin Fund and identified as being associated with the Central Utah Project. Funds are available for the O&M and the annual rate update will provide sufficient funding for those activities associated with Olmsted operations without negatively affecting funding available for other CUP activities. WAPA welcomes continued coordination and participation of interested parties in the development and application of the Olmsted rate.

Comment: Commenters questioned how much of the $837,670 is associated with historic preservation costs for converting the original power plant into a museum, as well as details of that work; the specific requirement(s) for preservation; the legal authority for including the costs as O&M; whether costs could be capitalized and repaid over forty years instead of expensed and repaid over 3 years; the intent regarding use of the facility as a museum and if it is intended to be accessible by the public.

Response: Upon review of future cost estimates, it has been determined that historic preservation costs, estimated at $500,000 per year for FY 2020 thru FY 2022, should be capitalized rather than expensed as initially presented at the November 17, 2017, public information forum. This is reflected in Table 1 and was posted to the website on February 14, 2018. The original Olmsted Powerhouse is listed on the National Register of Historic Places and scheduled tours will be conducted in the renovated museum. The structural improvements to the existing Powerhouse are outlined in Section 5 of the Memorandum of Agreement among CUWCD, Interior, and the Utah State Historic Preservation Officer that was signed in October 2014 and was posted along with the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) to the website on January 25, 2018.

Comment: Commenters questioned the funding source for the historical preservation work and whether non-reimbursable appropriations have been or could be requested/obtained in accordance with Section 8 of the CRSP Act.

Response: CRSP Act Section 8 funding will not be available. The Bureau of Reclamation's authorized construction cost ceiling for the Bonneville Unit M&I System was fully utilized. As a result, Olmsted is not authorized for additional construction appropriations.

Comment: Commenter expressed concern about a statement by WAPA during the public information forum that at the end of the contract period in 2024, the Olmsted Project may be included into CRSP. Customers asked for clarification and an explanation of what options WAPA is currently contemplating for Olmsted. Customers oppose any changes that would shift costs to CRSP.

Response: The marketing plan is not within the scope of this process. WAPA will seek public comments when it conducts a public process for the Post-2024 Marketing Plan prior to the end of the current Marketing Plan.

Availability of Information

Information about this rate schedule, including the customer rate brochure, PRSs, comments, letters, memorandums, and other supporting materials that were used to develop the Provisional Formula Rates, is available for inspection and copying at the Colorado River Storage Project

Management Center, 299 South Main Street, Suite 200, Salt Lake City, Utah. Many of these documents are also available on WAPA's website at *https://www.wapa.gov/regions/CRSP/rates/Pages/rate-order-177.aspx.*

Ratemaking Procedure Requirements

Environmental Compliance

In compliance with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321–4347; the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021), WAPA adopted the EA and FONSI prepared by the Central Utah Water District for the Olmsted Powerplant Replacement Project. In addition, WAPA has determined that the marketing of Olmsted power and the establishment of power rates for the marketing of that power are Federal actions that are categorically excluded from the preparation of an EA or an environmental impact statement. A copy of the categorical exclusion determination is available on WAPA's website at *https://www.wapa.gov/regions/RM/environment/Pages/CX2017.aspx.*

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no review of this Notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The Provisional Formula Rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the foregoing and under the authority delegated to me, I confirm and approve on an interim basis, effective the first full billing period on or after June 6, 2018, Rate Schedule F–1 for the Olmsted Powerplant Replacement Project of the Western Area Power Administration. This rate schedule shall remain in effect on an interim basis, pending the Federal Energy Regulatory Commission's confirmation and approval of it, or substitute rate, on a final basis through May 6, 2023, or until superseded.

Dated: April 30, 2018.

Dan Brouillette,

Deputy Secretary of Energy.

United States Department of Energy Western Area Power Administration

Colorado River Storage Project Management Center Olmsted Powerplant Replacement Project

Electric Power Service, (Approved Under Rate Order No. WAPA–177)

Effective

The first day of the first, full billing period beginning on or after June 6, 2018, and extending through May 6, 2023, or until superseded by another rate schedule, whichever occurs earlier.

Available

Within the marketing area served by the Colorado River Storage Project; parts of Northern Utah.

Applicable

To the sale of total plant generation to all customers with an Olmsted allocation.

Character

Alternating current, 60 hertz, three-phase, delivered and metered at the voltages and points established by contract.

Formula Rate

Annual Revenue Requirement = Projected OM&R Costs + Projected Interest + Projected Principal Payments ± True-Up Adjustment.

Adjustments

True-Up Adjustment: The surplus or deficit that occurred in the last historic year when actual costs and repayment obligations are subtracted from actual revenues.

Adjustment for Power Factor: The customer will be required to maintain a power factor at all points of measurement between 95 percent lagging and 95 percent leading.

[FR Doc. 2018–09623 Filed 5–4–18; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2018–0192; FRL–9976–55]

Dinotefuran; Receipt of Applications for Emergency Exemptions, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received specific exemption requests from the Delaware Department of Agriculture (DDA), the Maryland Department of Agriculture (MDA), the Pennsylvania Department of Agriculture (PDA) and the Virginia Department of Agriculture and Consumer Services (VDACS) to use the insecticide dinotefuran (CAS No. 165252–70–0) to treat up to 58,118 acres of pome and stone fruits to control the brown marmorated stinkbug. The applicants propose uses which are supported by the Interregional Research Project Number 4 (IR–4) and have been requested in 5 or more previous years, and petitions for tolerances have not yet been submitted to the Agency. Therefore, EPA is soliciting public comment before making the decision whether to grant the exemptions.

DATES: Comments must be received on or before May 22, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2018–0192, by one of the following methods:

- *Federal eRulemaking Portal: https://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.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

• Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.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, 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 pesticide(s) discussed in this document, compared to the general population.

II. What action is the agency taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. The DDA, MDA, PDA and VDACS have requested the EPA Administrator to issue specific exemptions for the use of dinotefuran on pome and stone fruits to control the brown marmorated stinkbug. Information in accordance with 40 CFR part 166 was submitted as part of the requests.

As part of the requests, the applicants assert that the rapid spread of large outbreaks of the brown marmorated stinkbug (a recent invasive species) resulted in an urgent and non-routine pest control situation that is expected to cause significant economic losses without the requested uses. The Applicants propose to make no more than two applications at a rate of 0.203 to 0.304 lb. (maximum of 0.608 lb.) of dinotefuran per acre, on up to 58,118 acres of pome and stone fruit grown in Delaware, Maryland, Pennsylvania and Virginia from April 1 to October 15, 2018. A total of 35,335 lbs. of dinotefuran could be used (maximum acreage at highest rate).

This notice does not constitute a decision by EPA on the applications themselves. The regulations governing FIFRA section 18 at 40 CFR 166.24(7), require publication of a notice of receipt of an application for a specific exemption proposing a use which is supported by the Interregional Research Project Number 4 (IR–4) and has been requested in 5 or more previous years, and a petition for tolerance has not yet been submitted to the Agency. The notice provides an opportunity for public comment on the application. The Agency, will review and consider all comments received during the comment period in determining whether to issue the specific exemptions requested by the DDA, MDA, PDA and VDACS.

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 17, 2018.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2018–09650 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[9975–98–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Tennessee's request to revise one of its EPA-authorized air programs to allow electronic reporting.

DATES: EPA approves of the State of Tennessee's air authorized program revision as of May 7, 2018].

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On March 9, 2018, the Tennessee Department of Environment and Conservation (TDEC) submitted an application titled ''State and Local Emissions Inventory System'' for revision to its EPA-approved program under title 40 CFR to allow new electronic reporting. EPA reviewed TDEC's request to revise its EPA-authorized Part 52—Approval and Promulgation of Implementation Plans program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Tennessee's request to revise/modify its Part 52—Approval and Promulgation of Implementation Plans program to allow electronic reporting

under 40 CFR parts 50–52 is being published in the **Federal Register**.

TDEC was notified of EPA's determination to approve its application with respect to the authorized program listed above.

Matthew Leopard,

Director, Office of Information Management.

[FR Doc. 2018–09607 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9977–57–Region 10]

Re-issuance of a General NPDES Permit (GP) for Small Suction Dredges in Idaho

Correction

In notice document 2018–09317 appearing on page 19281 in the issue of Wednesday, May 2, 2018, make the following correction:

In the third column, under the **DATES** heading, in the fifth line ''May 2, 2018'' should read ''June 1, 2018''.

[FR Doc. C1–2018–09317 Filed 5–4–18; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

[9976–86–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of North Dakota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of North Dakota's request to revise its National Primary Drinking Water Regulations Implementation EPA-authorized program to allow electronic reporting.

DATES: EPA approves the authorized program revision for the State of North Dakota's National Primary Drinking Water Regulations Implementation as of June 6, 2018, if no timely request for a public hearing is received and accepted by the Agency.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On March 22, 2018, the North Dakota Department of Health (ND DOH) submitted an application titled ''Compliance Monitoring Data Portal'' for revision to its EPA-approved drinking water program under title 40 CFR to allow new electronic reporting. EPA reviewed ND DOH's request to revise its EPA-authorized program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve North Dakota's request to revise its Part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting under 40 CFR part 141 is being published in the **Federal Register**.

ND DOH was notified of EPA's determination to approve its application with respect to the authorized program listed above.

Also, in today's notice, EPA is informing interested persons that they may request a public hearing on EPA's action to approve the State of North Dakota's request to revise its authorized public water system program under 40 CFR part 142, in accordance with 40 CFR 3.1000(f). Requests for a hearing must be submitted to EPA within 30 days of publication of today's **Federal Register** notice. Such requests should include the following information:

(1) The name, address and telephone number of the individual, organization or other entity requesting a hearing;

(2) A brief statement of the requesting person's interest in EPA's determination, a brief explanation as to why EPA should hold a hearing, and any other information that the requesting person wants EPA to consider when determining whether to grant the request;

(3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

In the event a hearing is requested and granted, EPA will provide notice of the hearing in the **Federal Register** not less than 15 days prior to the scheduled hearing date. Frivolous or insubstantial requests for hearing may be denied by EPA. Following such a public hearing, EPA will review the record of the hearing and issue an order either affirming today's determination or rescinding such determination. If no timely request for a hearing is received and granted, EPA's approval of the State of North Dakota's request to revise its part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting will become effective 30 days after today's notice is published, pursuant to CROMERR section 3.1000(f)(4).

Matthew Leopard,

Director, Office of Information Management.

[FR Doc. 2018–09606 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2018–0013, FRL–9977–63–OEI]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Revisions to the RCRA Definition of Solid Waste (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an

information collection request (ICR), Revisions to the RCRA Definition of Solid Waste (EPA ICR No. 2310.06, OMB Control No. 2050–0202) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through April 30, 2018. Public comments were previously requested via the **Federal Register** on February 26, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before June 6, 2018.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2018–0013, to (1) EPA, either online using *www.regulations.gov* (our preferred method), or by email to *rcra-docket@epa.gov,* or by mail to: RCRA Docket (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Tracy Atagi, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 703–308–8672; fax number: 703–308–8880; email address: *atagi.tracy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: In 2015, the EPA published final revisions to the definition of solid waste that exclude certain hazardous secondary materials from regulation. The information requirements help ensure that (1) entities operating under the regulatory exclusions contained in today's action are held accountable to the applicable requirements; (2) state inspectors can verify compliance with the restrictions and conditions of the exclusions when needed; and (3) hazardous secondary materials exported for recycling are actually handled as commodities abroad. The United States Court of Appeals for the District of Columbia Circuit on July 7, 2017, and amended on March 6, 2018, issued orders vacating certain provisions of the 2015 rule and reinstated corresponding provisions from the 2008 rule. The vacatur went into effect when the court issued its mandate on March 14, 2018. Paperwork requirements finalized in the 2015 rule, as amended by the court-issued mandate, include:

- Under the generator-controlled exclusion at 40 CFR 261.4(a)(23), the tolling contractor has to maintain at its facility for no less than three years records of hazardous secondary materials received pursuant to its written contract with the tolling manufacturer, and the tolling manufacturer must maintain at its facility for no less than three years records of hazardous secondary materials shipped pursuant to its written contract with the tolling contractor. In addition, facilities performing the recycling of hazardous secondary materials under the generator-controlled exclusions at 40 CFR 261.4(a)(23) to maintain documentation of their legitimacy determination onsite.
- Under the transfer-based exclusion at 40 CFR 261.4(a)(24), a generator sending secondary hazardous materials to a facility that does not have a permit, would be required to conduct a ''reasonable efforts'' environmental audit of the receiving facility; and a hazardous secondary materials recycler must meet the following conditions: having financial assurance in place, having trained personnel, and meeting emergency preparedness and response conditions.
- Under the export requirements of the transfer-based exclusion at 40 CFR 261.4(a)(25), exporters of hazardous secondary material must provide notice and obtain consent of the receiving country, and file an annual report.
- Under the remanufacturing exclusion at 40 CFR 261.4(a)(27), both the hazardous secondary material generator and the remanufacturer must maintain records of shipments and confirmations of receipts for a period of three years from the dates of the shipments.
- Under the revised speculative accumulation requirement in 261.1(c)(8), all persons subject to the speculative accumulation requirements must label the storage unit by indicating the first date that the material began to be accumulated.

This ICR renewal does not include the burden associated with filling out form 8700–12 because that burden is included under OMB Control Number 2050–0024. The remaining burden will eventually be included in ICR 2050–0053, at which time this ICR will be discontinued.

Form Numbers: None.

Respondents/affected entities: Private business or other for-profit entities, as well as State, Local, or Tribal governments.

Respondent's obligation to respond: Required to obtain or retain a benefit (42 U.S.C. 6921, 6922, 6923, and 6924).

Estimated number of respondents: 7,674.

Frequency of response: On occasion.

Total estimated burden: 34,883 hours per year. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $2,752,557 (per year), which includes $15,475 annualized capital or operation & maintenance costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018–09605 Filed 5–4–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of Intent To Terminate Receiverships

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for the institutions listed below, intends to terminate its receivership for said institutions.

Fund	Receivership name	City	State	Date of appointment of receiver
10460	Excel Bank	Sedalia	MO	10/19/2012
10035	Alliance Bank	Culver City	CA ..	02/06/2009
10459	First United Bank	Crete	IL	09/28/2012

The liquidation of the assets for each receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receiverships will serve no useful purpose. Consequently, notice is given that the receiverships shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of any of the receiverships, such comment must be made in writing, identify the receivership to which the comment pertains, and be sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of the above-mentioned receiverships will be considered which are not sent within this time frame.

Dated at Washington, DC, on May 2, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–09666 Filed 5–4–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, May 10, 2018 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC (12th Floor)

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Correction and Approval of Minutes for March 8, 2018

Draft Advisory Opinion 2018–04: Conservative Primary LLC

Draft Advisory Opinion 2018–06: Liuba for Congress

Internet Communication Disclaimers Illustrative Examples

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Dayna C. Brown,

Secretary and Clerk of the Commission.

[FR Doc. 2018–09804 Filed 5–3–18; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1607]

Policy on Payment System Risk and Expanded Real-Time Monitoring

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice; request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is requesting comment on the benefits and drawbacks of a potential change to part II of the Federal Reserve Policy on Payment System Risk (PSR policy). The potential change would entail the Federal Reserve Banks (Reserve Banks) monitoring in real time all Fedwire Funds transfers and rejecting those transfers that would breach the Fedwire sender's net debit cap, that is, the ceiling on its total daylight overdraft position that it is permitted to incur in its Federal Reserve account during any given day. If, after an evaluation of the public comments on this notice, the Board concludes that an expansion of real-time monitoring is desirable, the Board will request public comment on specific proposed changes to the PSR policy.

DATES: *Applicable Date:* Comments must be received by July 6, 2018.

ADDRESSES: You may submit comments, identified by Docket No. OP–1607, by any of the following methods:

- *Agency website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove sensitive personal information at the commenter's request. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Jeff Walker, Assistant Director (202–721–4559), Jason Hinkle, Manager (202–912–7805), or Michelle D. Olivier, Senior Financial Services Analyst (202–452–2404), Division of Reserve Bank Operations and Payment Systems; Evan Winerman, Counsel (202–872–7578), Legal Division.

SUPPLEMENTARY INFORMATION:

I. Background

Part II of the Board's PSR policy seeks to balance the costs and risks associated with the provision of Federal Reserve intraday credit (or daylight overdrafts) against the benefits of intraday liquidity. The PSR policy recognizes that the Federal Reserve has an important role in providing intraday credit to foster the smooth functioning of the overall payment system and also seeks to control the risks assumed by the Reserve Banks in providing this intraday credit.

The Reserve Banks provide intraday liquidity by way of supplying temporary, intraday credit to healthy depository institutions, and the Reserve Banks could face direct risk of loss should institutions be unable to settle their daylight overdrafts in their Federal Reserve accounts before the end of the day. The Reserve Banks control their exposures through several methods, including by incentivizing institutions to voluntarily collateralize daylight

overdrafts, setting limits (net debit caps) on daylight overdrafts in institutions' Federal Reserve accounts, and requiring collateral in certain situations. In addition, Reserve Banks have the ability to monitor an institution's Federal Reserve account activity in real time and reject certain transactions that would cause an overdraft in excess of the institution's net debit cap; this capability is known as ''real-time monitoring.'' [1] Real-time monitoring allows the Reserve Banks to prevent an institution from transferring funds from an account that lacks sufficient funds or overdraft capacity to cover the payment(s).[2]

The Board is conducting a review of the Federal Reserve's intraday credit policies related to real-time monitoring and is exploring the potential benefits that expanded real-time monitoring for Fedwire Funds may have in reducing the risk that payments activity, including errant or fraudulent payments, poses to any institution that maintains a Federal Reserve account. A risk-focused expansion in the use of the real-time monitor may provide additional account protection against mismanagement or misuse of payment services and could help mitigate risks for both institutions and the Reserve Banks.

In 2001, the Board requested comment on expanding real-time monitoring capabilities to all transactions subject to settlement-day finality for all institutions but ultimately decided not to pursue the expansion.[3] At the time of the previous request for comment, applying the real-time monitoring technology to an institution's account would have resulted in both Fedwire funds transfers and National Settlement Service (NSS) transactions being rejected, and would have necessitated that the institution prefund its automated clearinghouse (ACH) credit originations. Commenters indicated that monitoring ACH credit originations and requiring institutions to prefund them might be overly burdensome to institutions and disruptive to the payment system overall. Since the 2001 proposal, the Federal Reserve has enhanced the functionality of the real-time monitoring technology to permit more selective application by payment type. During this period, depository institutions and their supervisors have dedicated greater attention to the risks associated with fraudulent transactions, notably those stemming from illicit or unauthorized penetration of institutions' information processing systems.

The Reserve Banks recently implemented a voluntary, no-cost pilot program for the real-time monitoring of Fedwire funds transfers, available to institutions with total assets under $50 billion.[4] Effective October 2, 2017, any Fedwire funds transfer that would cause (or increase) an overdraft in a participating institution's Federal Reserve account in excess of its net debit cap is rejected, unless the institution has specifically opted out of the program. A rejection gives the participating institution an additional opportunity to verify authorization and authenticity and to fund the transaction, and limits the associated financial risk to both the institution and its Reserve Bank. The Reserve Banks expect this program will provide risk mitigation benefits for the participating institutions as well as the Reserve Banks. In addition, the program should allow Reserve Banks and institutions to assess the potential benefits and drawbacks of routine real-time monitoring of all Fedwire funds transfers.

The policy change under consideration by the Board would amend the PSR policy to apply real-time monitoring as a mandatory practice for all institutions, regardless of total asset size. The potential policy change, as discussed below, would apply real-time monitoring only to institutions' outgoing Fedwire funds transfers.

II. Potential Policy Change: Monitoring in Real Time All Institutions' Fedwire Funds Payments

The Board is exploring the benefits and drawbacks of a real-time monitoring expansion for Fedwire funds transfers (RTME), which is defined as using the Reserve Banks' real-time monitoring technology to reject any outgoing Fedwire funds transfer that would cause any institution's overdrafts to exceed its net debit cap.[5] Taking a risk-focused approach, the Board is only considering real-time monitoring for Fedwire funds transfers because these transactions can be high-value and settle immediately and irrevocably, and therefore represent a potentially greater credit risk to both the Reserve Banks and Fedwire senders than transactions with typically lower per-transfer values or without settlement-day finality. Fedwire funds payments represent the majority of the dollar value of payments that the Reserve Banks process, and in 2016, Fedwire funds activity totaled approximately $767 trillion, with an average transaction value of $5.2 million.[6] If a payor institution does not fund its settlement with the Reserve Bank for transactions that do not have settlement-day finality, such as checks and ACH debit transactions, the Reserve Bank may return or reverse the transactions. As a consequence, those transactions pose less risk to the Reserve Banks in the event the payor institution defaults. The Board is not at this time considering monitoring and rejecting payments other than Fedwire funds, such as Fedwire securities transfers, NSS transactions, ACH credit transactions, or cash withdrawals. Furthermore, the Board is not seeking comment on existing policies related to real-time monitoring and rejecting payments for institutions that fall within established parameters for such treatment, including those in weakened financial condition.

RTME could benefit institutions and the Reserve Banks by providing additional account management and cyber, fraud, and credit risk controls for Fedwire funds transfers, supplementing institutions' internal account management and risk controls.[7] Specifically, RTME could assist institutions in managing their Federal Reserve accounts in compliance with the PSR policy by preventing

[1] The Reserve Banks monitor all institutions' account activity for compliance with the daylight overdraft posting rules on an after-the-fact or ex post basis. Real-time monitoring supplements but does not replace Reserve Banks' ex post monitoring.

[2] Under the current PSR policy, a Reserve Bank will apply real-time monitoring selectively to an individual institution's position when the Reserve Bank believes that it faces excessive risk exposure, for example, from a problem institution or an institution with chronic overdrafts in excess of what the Reserve Bank determines is prudent. An institution not considered to pose an excessive risk exposure may voluntarily elect to have its account monitored in real time, subject to approval by its Reserve Bank.

[3] The request for comment and the subsequent notice of the Board's decision not to pursue the proposed real-time monitoring changes can be found, respectively, at 66 FR 30208 (June 5, 2001) and 67 FR 54424 (August 22, 2002).

[4] Participation in the pilot program is restricted to institutions not currently on the monitor at the direction of their Reserve Bank. The Reserve Banks continue to apply real-time monitoring on an involuntary basis to individual institutions when the account-holding Reserve Bank believes that the account relationship poses an excessive risk exposure.

[5] In certain circumstances and subject to Reserve Bank approval, institutions may pledge collateral to their Reserve Banks to secure daylight overdraft capacity in excess of their debit caps, known as maximum overdraft capacity or max cap. For purposes of this notice, net debit cap refers to both institutions' standard net debit caps as well as any additional collateralized capacity approved by their Reserve Banks.

[6] For comparison, the average transaction values for commercial ACH and check transactions processed by the Reserve Banks were approximately $1,700 and $1,500, respectively.

[7] Account management tools provided by the Reserve Banks, including real-time monitoring, are intended to supplement rather than replace institutions' independent account management and risk controls.

institutions from breaching their net debit caps with Fedwire funds payments. Because of the heightened cyber risk environment and unexpected nature of fraudulent funds transactions, an institution's overdraft could exceed its net debit cap and the institution might not have the resources to cover the overdraft. RTME would protect against both fraudulent and authorized Fedwire funds transfers that would result in an overdraft in excess of an institution's net debit cap. Expansion of the current limited real-time monitoring pilot to all institutions would provide these account management and risk mitigation benefits to more institutions' Federal Reserve accounts. By further transitioning to a mandatory program, RTME would ensure consistent treatment of all institutions' Fedwire funds activity. Additionally, a mandatory program would make certain that the Reserve Banks' risk of loss from a defaulting institution's Fedwire funds transfers would be restricted to each account's established net debit cap.

While RTME could mitigate risks for the Reserve Banks and institutions that hold Federal Reserve accounts, the Board is interested in understanding any concerns about potential negative consequences. For example, RTME could increase the risk of payment delays or gridlock. In the event of a rejected Fedwire funds transfer, RTME would require an institution to review and, if appropriate, fund and resubmit the transfer, requiring prompt account management to avoid delay. A delay caused by a rejected transfer may adversely affect the intended receiver and similarly require account management adjustments should the funds fail to arrive when expected. An institution that is closely managing to its net debit cap to avoid the rejection of Fedwire funds transfers may choose to throttle payments during the day, restricting and delaying funds transfers until sufficient funds are available. As a consequence, the receiver of these Fedwire funds transfers will not obtain the funds until later than it otherwise would have and may likewise choose to throttle payments.

To analyze the potential for rejected payments, the Board reviewed institutions' recent Fedwire funds activity against their net debit caps. Analysis of 2016 annual payment data indicates that RTME would have rejected less than 0.003 percent of the approximately 133 million Fedwire funds transfers sent by institutions that may be covered by the program.[8] In terms of value, only 0.002 percent of the over $484 trillion of Fedwire funds transfers sent by these institutions would have been affected. Approximately 5 percent of these institutions would have had at least one Fedwire funds transfer rejected per year under RTME.[9] As a result of this initial analysis, the Board estimates that under current conditions and payment activities, most institutions covered by the proposed RTME program would not experience rejected payments.

Although RTME appears unlikely to disrupt the payment system in the aggregate, the Board recognizes the potential for unintended consequences that may not be evident by analyzing historical payments data, possibly associated with certain institution types or payments activity functioned through Federal Reserve accounts. To better assess the potential benefits and negative effects of such a program, the Board is soliciting feedback on expanding real-time monitoring to all Fedwire funds transfers and is particularly interested in any negative consequences of RTME not identified in this notice. Should the Board choose to move forward with developing and implementing an RTME program, the Board will request public comment on a specific RTME proposal.

III. Request for Comment

The Board is seeking comment on all aspects of a potential mandatory, expanded real-time monitoring program that would monitor and reject Fedwire funds payments sent by all institutions. As described previously, an RTME program would reject any Fedwire funds transfer that would breach the Fedwire funds sender's net debit cap, as established under part II of the PSR policy.

The Board also requests comment on the following specific questions regarding a potential RTME program:

1. What would be the benefits and drawbacks of a mandatory RTME program to institutions' operations and funding? Are there characteristics of an RTME program that could mitigate any potential drawbacks?

2. Would RTME lead to significantly greater payment delays, or would it have a negligible effect? Would real-time monitoring of Fedwire funds transfers at the net debit cap level affect the way institutions manage their Federal Reserve accounts with respect to daylight overdrafts? Would an RTME program cause institutions to delay sending payments?

3. Would RTME lead your institution to apply for a higher net debit cap in order to avoid rejection of Fedwire funds transfers?

4. If your institution participates or participated in the Enhanced Overdraft Protection Tool (EOPT) pilot program, please describe your experience.

5. If the Federal Reserve implemented a mandatory RTME program, how would this action affect your institution's payments business going forward? Would RTME encourage institutions to move their large-dollar payments activity from Fedwire funds to other payment channels? What operational or risk challenges would this movement present?

6. Does your institution currently have programs and practices in place that address the risk of an errant or fraudulent payment, particularly those that might result in an excessive overdraft? If a mandatory RTME policy were adopted, would those programs and practices be kept or replaced? Does having certain programs and practices in place provide the institution or Federal Reserve a sufficient reduction in risk to warrant exclusion from a mandatory RTME program?

IV. Competitive Impact Analysis

The Board has established procedures for assessing the competitive impact of rule or policy changes that have a substantial impact on payment system participants.[10] Under these procedures, the Board will assess whether a change would have a direct and material adverse effect on the ability of other service providers to compete effectively

[8] Analysis excludes the secondary impact that a rejected Fedwire funds transfer might have on the funding of the receiving institution's outgoing Fedwire funds transfers.

[9] The Board also reviewed institutions' intraday credit use in 2016 and found that most institutions did not fully use their daylight overdraft capacity—in fact, approximately 80 percent of institutions used less than 25 percent of their capacity for their peak overdraft. The Board recognizes that historically high levels of reserve balances have decreased the need for intraday credit for some institutions. For comparison, the Board reviewed peak cap utilization in 2007, during which approximately 50 percent of institutions used less than 25 percent of their capacity for their peak overdraft and the vast majority of institutions, over 80 percent, never exceeded their net debit cap at any time during the year. In addition, many institutions currently maintain net debit caps below the maximum level that would be permitted under the PSR policy; such institutions could request a higher net debit cap, which would likely alleviate potential payment disruptions as the institutions adjust their account management behavior or balances in response to RTME. For example, approximately 80 percent of institutions with a positive net debit cap have an exempt cap, and these institutions could double their daylight overdraft capacity by requesting a *de minimis* cap with only a marginal increase in administrative burden to the institution.

[10] These procedures are described in the Board's policy statement ''The Federal Reserve in the Payments System,'' as revised in March 1990. 55 FR 11648 (March 29, 1990).

with the Federal Reserve in providing similar services due to differing legal powers or constraints, or due to a dominant market position of the Federal Reserve deriving from such differences. If no reasonable modifications would mitigate the adverse competitive effects, the Board will determine whether the anticipated benefits are significant enough to proceed with the change despite the adverse effects.

The Board does not anticipate that RTME would have a direct and material impact on the ability of other service providers to compete effectively with the Reserve Banks' payment services but requests comment on that issue and on whether, even if there are adverse competitive effects, they are outweighed by the potential benefits of RTME. If the Board chooses to move forward with developing and implementing an RTME program, the Board will evaluate these options under its competitive impact procedures.

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

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–09622 Filed 5–4–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 5, 2018.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Benc Holdings, Inc., Coon Rapids, Minnesota;* to become a bank holding company by acquiring up to 100 percent of KES Bancshares, Inc., Virginia, Minnesota, and thereby indirectly acquire shares of Northern State Bank, Virginia, Minnesota.

Board of Governors of the Federal Reserve System, May 2, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–09645 Filed 5–4–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 5, 2018.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566. Comments can also be sent electronically to *Comments.applications@clev.frb.org:*

1. *Dollar Mutual Bancorp, Pittsburgh, Pennsylvania;* to acquire 100 percent of the voting shares of Dollar Bank, FSB, Pittsburgh, Pennsylvania, upon its conversion from mutual to stock form.

Board of Governors of the Federal Reserve System, May 2, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–09644 Filed 5–4–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 21, 2018.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Ann R. Mock, Edmond, Oklahoma, Barry W. Mock, Altus, Oklahoma, and the Mock Irrecocable Trust and its co-trustee Rick Cheanye, both of Altus, Oklahoma;* to retain shares of First Altus Bancorp, and thereby retain shares of Frazer Bank, both of Altus, Oklahoma.

Board of Governors of the Federal Reserve System, May 2, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–09643 Filed 5–4–18; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2018–02; Docket No. 2018–0002; Sequence No. 6]

Request for Comment: New Federal Real Property Profile Information for Communications Facility Installation

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Request for comment.

SUMMARY: The General Services Administration is seeking input on the inclusion of communications facility installation information into the Federal Real Property Profile (FRPP).

DATES: This notice is effective July 6, 2018.

ADDRESSES: Submit comments in response to Notice-MA–2018–02 by any of the following methods:

- *Regulations.gov*: *http://www.regulations.gov.* Submit comments via the Federal Rulemaking portal by entering ''Notice-MA–2018–02'', under the heading ''Keyword or ID'' and select ''Search''. Select the link ''Submit a Comment Now'' that corresponds with ''Notice–MA–2018–02, and follow the instructions provided on the screen. Please include your name, company name (if applicable), and ''Notice–MA–2018–02'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Lois Mandell, 1800 F Street NW, Washington, DC 20405.

GSA requests that comments be as specific as possible, include any supporting data, detailed justification for your specific suggestions regarding information to add to the FRPP related to the installation of communications facilities on Federal real property.

FOR FURTHER INFORMATION CONTACT: For further information on this document, please contact Chris Coneeney, Realty Specialist, Office of Government-wide Policy, 202–208–2956 or *chris.coneeney@gsa.gov.*

For information pertaining to the status or publication schedules, contact the Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, 202–501–4755. Please cite Notice MA–2018–02.

SUPPLEMENTARY INFORMATION: On March 23, 2018, the President signed HR 1625, ''Consolidated Appropriations Act, 2018,'' which provided appropriations through fiscal year 2018. Section 608 of the law directs GSA to issue a notice for public comment regarding the inclusion of a communications facility installation under section 21 of the Federal Assets Sale and Transfer Act of 2016 (40 U.S.C. 1303 note) (FASTA).

The statute defines communications facility installation as any infrastructure, including any transmitting device, tower, or support structure, and any equipment, switches, wiring, cabling, power sources, shelters, or cabinets associated with the licensed or permitted unlicensed wireless or wireline transmission of writings, signs, signals, data, images, pictures, and sounds of any kind; and any antenna or apparatus that is designed for the purpose of emitting radio frequency; is designed to be operated, or is operating, from a fixed location pursuant to authorization by the Federal Communications Commission or is using duly authorized devices that do not require individual licenses; and is added to a tower, building, or other structure.

This Notice is requesting recommendations on (a) the criteria that make Federal real property capable of supporting communications facility installations; (b) the types of information related to the Federal real property that should be included in the Federal Real Property Profile (FRPP) database; (c) additional data related to installing a communication facility on Federal real property that should be considered, such as the types of real property best suited for a communication facility installation; and (d) locations that may be a higher priority based on market needs or gaps in various communication services, such as broadband or cellular services.

The FRPP is a centralized database containing descriptive information on Federal real property owned, leased or otherwise managed by executive branch agencies. Executive agencies submit real property data to the FRPP pursuant to section 21 of FASTA. A current list and associated definitions of FRPP data elements and reporting requirements are contained in the Federal Real Property Council Guidance on Real Property Inventory Reporting and can be found at: *https://www.gsa.gov/cdnstatic/FY%202017%20FRPP%20DATA%20DICTIONARY%20V2_0.pdf.*

Although the agency may not respond to each individual comment, GSA may follow-up with respondents to clarify comments. GSA values public feedback and will consider all input that it receives.

Dated: May 2, 2018.

Alexander J. Kurien,

Deputy Associate Administrator, Office of Asset and Transportation Management, Office of Government-wide Policy.

[FR Doc. 2018–09671 Filed 5–4–18; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Plan for Foster Care and Adoption Assistance: Title IV–E of the Social Security Act OMB No.: 0970–0433.

Description

A title IV–E plan is required by section 471, part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, adoption assistance and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization or tribal consortium (Tribe) to operate a title IV–E program in the same manner as a State with minimal exceptions. The Tribe must have an approved title IV–E Plan. The title IV–E plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State or Tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by the Children's Bureau of the Administration for Children and Families or a different format, on the condition that the format used includes all of the title IV–E plan requirements of the law.

Respondents: Title IV–E agencies administering or supervising the administration of the title IV–E programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E Plan	17	1	16	272

Estimated Total Annual Burden Hours: 272.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–09581 Filed 5–4–18; 8:45 am]

BILLING CODE 4184–01–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; Small Health Care Provider Quality Improvement Program, OMB No. 0915–0387—Revision

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. HRSA published the 60-Day notice on January 8, 2018, FR Doc. 2018–00173. 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.

DATES: Comments on this ICR should be received no later than June 6, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Small Health Care Provider Quality Improvement Program, OMB No. 0915–0387—Revision.

Abstract: This program is authorized by Title III, Public Health Service Act, Section 330A(g) (42 U.S.C. 254c(g)), as amended. This authority permits the Federal Office of Rural Health Policy (FORHP) to support grants that expand access to, coordinate, contain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of health care networks in rural and frontier areas and regions. The authority also allows HRSA to provide funds to rural and frontier communities to support the direct delivery of health care and related services, expand existing services, or enhance health service delivery through education, promotion, and prevention programs.

The purpose of the Small Health Care Provider Quality Improvement Grant (Rural Quality) Program is to provide support to rural primary care providers for implementation of quality improvement activities. The program promotes the development of an evidence-based culture and delivery of coordinated care in the primary care setting. Additional objectives of the program include improved health outcomes for patients, enhanced chronic disease management, and better engagement of patients and their caregivers. Organizations participating in the program are required to use an evidence-based quality improvement model; develop, implement and assess effectiveness of quality improvement initiatives; and use health information technology (HIT) to collect and report data. HIT may include an electronic patient registry or an electronic health record, and is a critical component for improving quality and patient outcomes. With HIT, it is possible to generate timely and meaningful data, which helps providers track and plan care.

Need and Proposed Use of the Information: FORHP collects this information to quantify the impact of grant funding on access to health care, quality of services, and improvement of health outcomes. FORHP uses the data for program improvement, and grantees use the data for performance tracking. The measures encompass access to care, population demographics, consortium/network, sustainability, quality improvement implementation strategies, clinical; and optional topic utilization.

The proposed Rural Quality draft measures reflect a reduced number of required measures and improvements to the number of optional measures including the following: 24 total measures (previously 43), which includes 16 required measures applicable to all awardees in addition to improved optional measure choices for 8 total optional measures (previously 4). Proposed revisions specifically include the following: (1) Alignment of clinical measures to current National Quality Forum endorsement recommendations and (2) broadened orientation of measures for improved applicability across variety of rural quality improvement project topic areas.

With the continuing shift in the healthcare environment towards provision of value-based care and utilization of reimbursement strategies through Centers for Medicare and Medicaid quality reporting programs, the latest competitive cohort also aligns with this shift. An increased number of sophisticated applicants leveraging increasingly intricate reporting methodologies for quality data collection, utilization, and analysis has resulted in an estimate of burden hours more in line with the realities of the health care landscape.

Likely Respondents: The respondents would be award recipients of the Small Health Care Provider Quality Improvement 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
Small Health Care Provider Quality Improvement Program Performance Improvement Measurement System (PIMS) Measurement	32	1	32	22	704
	32	.....	32	.....	704

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–09674 Filed 5–4–18; 8:45 am]

BILLING CODE 4165–15–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; Rural Health Opioid Program Grant Performance Measures, OMB No. 0906–xxxx—NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with 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. HRSA published the 60-day notice on December 15, 2017, FR Doc. 2017–27013. HRSA received one comment. 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.

DATES: Comments on this ICR should be received no later than June 6, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Opioid Program Grant Performance Measures

OMB No. 0906–xxxx—NEW

Abstract: The Rural Health Opioid Program aims to promote rural health care services outreach by expanding the delivery of opioid related health care services to rural communities. The program will work to reduce the morbidity and mortality related to opioid overdoses in rural communities through the development of broad community consortiums to prepare individuals with opioid-use disorder to start treatment, implement care coordination practices to organize patient care activities, and support individuals in recovery through the enhancement of behavioral counselling and peer support activities.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Target population demographics; (b) referrals to substance abuse treatment; (c) substance abuse treatment process and outcomes; (d) education of health care providers and community members; and (e) rates of fatal and non-fatal opioid-related overdose. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents would be recipients of the Rural Health Opioid Program grant funding.

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
Rural Health Opioid Program Grant Performance Measures	10	1	10	11	110
Total	10		10		110

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–09668 Filed 5–4–18; 8:45 am]

BILLING CODE 4165–15–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 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel PHS, 2017–1 NIAID Topic 43 (Adjuvant Development).

Date: May 30, 2018.

Time: 10:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–507–9685, *thomas.conway@nih.gov.*

(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 2, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–09659 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Antibodies Against TL1A, a TNF-Family Cytokine, for the Treatment and Diagnosis of Crohn's Disease, Ulcerative Colitis, Asthma, Psoriasis and Biliary Cirrhosis

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute (''NHLBI''), an institute of the National Institutes of Health; an agency within the Department of Health and Human Services, is contemplating the grant of an exclusive patent license to commercialize the invention(s) embodied in the intellectual property estate stated in the Summary Information section of this notice to Precision IBD, Inc., located in San Diego, California, and incorporated under the laws of Delaware.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development on or before May 22, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Cristina Thalhammer-Reyero, Ph.D., MBA, Senior Licensing and Patenting Manager, NHLBI Office of Technology Transfer and Development, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; Telephone: +1–301–435–4507; Fax: +1–301–594–3080; Email: *thalhamc@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

U.S. Provisional Patent Application No. 61/488,671, filed May 20, 2011; PCT Application. No. PCT/US2012/028926, filed March 13, 2012; U.S. Patent No. 9,068,003, issued June 30, 2015; U.S. Patent No. 9,896,511, issued February 20, 2018; and U.S. Patent Application No. 15/872,592, filed January 16, 2018, ''Antibodies Against TL1A, a TNF-Family Cytokine, for the Treatment and Diagnosis of Autoimmune Inflammatory Diseases'', NIH Reference No. E–073–2011/0,1,2.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: ''Development and commercialization of antibodies against TL1A for the treatment and diagnosis of Crohn's Disease, Ulcerative Colitis, Asthma, Psoriasis and Biliary Cirrhosis''

The subject technology is based on the use of antibodies against TL1A, a TNF-Family cytokine, for the treatment and diagnosis of autoimmune inflammatory diseases. Autoimmune inflammatory diseases occur in greater than five percent of the U.S. population. Treatments generally include immunosuppressants or anti-inflammatory drugs, which can have serious side effects. Recently, more specific immunomodulatory therapies such as TNF-alpha antagonists have been developed. In experiments with

mice, NIAMS inventors have shown that the interaction between the TNF family ligand TL1A with its receptor, DR3, is critical for development of disease in asthma, inflammatory bowel disease and multiple sclerosis. They have also developed anti-TL1A antibodies that prevent disease in mouse models of rheumatoid arthritis and inflammatory bowel disease. This invention describes anti-human TL1A monoclonal antibodies that may be useful for the development of diagnostics and therapeutics for autoimmune inflammatory diseases, as well as methods of treating such diseases by blocking the interaction between TL1A and DR3 by the described antibodies. This specific immunomodulatory effect provides potential for potent therapy without inducing global immunosuppression.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI Office of Technology Transfer and Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

The public may file comments or objections in response to this Notice. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 27, 2018.

Cristina Thalhammer-Reyero,

Senior Licensing and Patenting Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.

[FR Doc. 2018–09654 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used for Identifying Potential Developmental Toxicants

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for identifying potential developmental toxicants. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring.

DATES: Receipt of information: Deadline for receipt of information is June 15, 2018.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Deputy Director, NICEATM; email: *nicole.kleinstreuer@nih.gov;* telephone: (984) 287–3150.

SUPPLEMENTARY INFORMATION:

Background: NICEATM fosters the evaluation and promotion of alternative test methods for regulatory use and supports efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants that replace, reduce, or refine animal use. Testing a chemical's potential to cause developmental toxicity is required by multiple federal agencies for regulatory and other decision contexts, and can use large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to identify potential developmental toxicants. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo developmental toxicity test methods currently used by federal agencies for regulatory and other decision contexts. NICEATM also requests available data from in vivo developmental studies, human or animal studies, or accidental human exposures, using the same chemicals used to evaluate the alternative developmental toxicity test methods.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is June 15, 2018. Responses to this notice will be posted at: *https://ntp.niehs.nih.gov/go/dev-nonanimal.* Persons submitting responses will be identified on the web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM involvement in activities relevant to the development of alternative test methods. Information about NICEATM and ICCVAM can be found at *http://ntp.niehs.nih.gov/go/niceatm* and *http://ntp.niehs.nih.gov/go/iccvam.*

Dated: April 27, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–09661 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed 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: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group, Clinical Molecular Imaging and Probe Development.

Date: May 31–June 1, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crown Plaza Hotel, 11228 Lone Eagle Dr., Bridgeton, MO 63044.

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR 15–326: I/START R03 Grants Program.

Date: June 1, 2018.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Sensorimotor Integration Study Section.

Date: June 5, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry A Study Section.

Date: June 5–6, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW, Washington, DC 20036.

Contact Person: Anita Szajek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–827–6276, *anita.szajek@nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Lung Cellular, Molecular, and Immunobiology Study Section.

Date: June 5–6, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Baltimore Harbor Hotel, 101 West Fayette Street, Baltimore, MD.

Contact Person: George M. Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 2, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–09655 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: June 4–5, 2018.

Closed: June 04, 2018, 8:30 a.m. to 9:15 a.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: June 04, 2018, 9:30 a.m. to 4:30 p.m.

Agenda: Discussion of Program and Issues.

Place: Nat. Inst. of Environmental Health Sciences Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: June 05, 2018, 8:30 a.m. to 10:30 a.m.

Agenda: Discussion of Program and Issues.

Place: Nat. Inst. of Environmental Health Sciences Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Gwen W. Collman, Ph.D., Interim Director, Division of Extramural Research & Training, National Institutes of Health, Nat. Inst. of Environmental Health Sciences, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: May 2, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–09657 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Inner Curvature Charge Concentration Device For Tissue Laceration

Description of Technology: Left ventricular outflow tract obstruction is a life-threatening complication of transcatheter mitral valve replacement caused by septal displacement of the anterior mitral leaflet (AML). The AML is a mobile structure that physically separates inflow and outflow zones of the left ventricle. Preserving the AML during surgical mitral valve replacement can cause left ventricular outflow tract obstruction, either when the prosthesis struts protrude into the left ventricular outflow tract or when along redundant anterior leaflet prolapses into the left ventrical outflow tract. The invention relates to devices having monopolar or bipolar tissue lacerators for efficiently and safely cutting AMLs percutaneously by vaporizing target tissue with electrical energy. Exemplary devices include a wire partially covered by electrical insulation, where the wire is kinked and where the wire is exposed through the insulation at one or more exposed regions along or near the inner curvature of the kink. The wire is configured to conduct electrical energy through the exposed region(s) and through a tissue target positioned adjacent the inner curvature to lacerate the tissue target via the electrical energy. The tissue target can be a native or prosthetic heart valve leaflet in a patient's heart. An optional feature of the device also includes an irrigation catheter to displace blood from the electrode, concentrating current at the tissue and reducing char and coagulum formation.

Potential Commercial Applications:

- Prevention of iatrogenic left ventricular outflow tract obstruction following transcatheter mitral valve replacement
- Bioprosthetic aortic scallop intentional laceration

Development Stage:

- In vivo data available

Inventors: Robert Lederman, Jaffar Khan, Toby Rogers (all of NHLBI).

Intellectual Property: HHS Reference No. E–064–2018/0–US–01; U.S. Provisional Patent Application 62/633,791 filed February 22, 2018.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@nih.gov.*

Collaborative Research Opportunity: The National Institute of Environmental Health Sciences seeks statements of capability or interest from parties interested in collaborative research to further develop and evaluate, please contact Peg Koelble, Technology Development Specialist, Office of Technology Transfer, National Heart, Lung, and Blood Institute, Phone: 301.594.4095; *koelblep@nhlbi.nih.gov.*

Dated: April 26, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018–09656 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group; Behavior and Social Science of Aging Review Committee NIA—S.

Date: June 6–7, 2018.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, Denver Airport, 7001 Yampa Street, Denver, CO 80249.

Contact Person:

Kimberly Firth, Ph.D., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *kimberly.firth@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 2, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–09658 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

***Mononegavirales* Vectors Expressing Chimeric Antigens**

Description of Technology

Human respiratory syncytial virus (RSV) continues to be the leading viral cause of severe acute lower respiratory tract disease in infants and children

worldwide. A licensed vaccine or antiviral drug suitable for routine use remains unavailable. This invention relates to the use of murine pneumonia virus (MPV), a virus to which humans normally are not exposed to and that is not cross-protected with RSV, as a vector to express the RSV fusion (F) glycoprotein as an RSV vaccine candidate. The RSV F ORF was codon optimized. The RSV F ORF was placed under the control of MPV transcription signals and inserted at the first (rMPV–F1), third (rMPV29 F3), or fourth (rMPV–F4) gene position of a version of the MPV genome that contained a codon pair optimized L polymerase gene. The recovered viruses replicated *in vitro* as efficiently as the empty vector, with stable expression of RSV F protein. Replication and immunogenicity of rMPV–F1 and rMPV–F3 were evaluated in rhesus macaques following administration by the combined intranasal and intratracheal routes. Both viruses replicated at low levels in the upper and lower respiratory tract, maintained stable RSV F expression, and induced similar high levels of RSV-neutralizing serum antibodies that reached peak titers by fourteen (14) days post-vaccination. rMPV provides a highly attenuated yet immunogenic vector for the expression of RSV F protein, with potential application in RSV-naïve and RSV experienced populations.

The invention relates to live, chimeric non-human *Mononegavirales* vectors that allow a cell to express at least one protein from at least one human pathogen as well as compositions comprising the vectors, methods and kits for eliciting an immune response in a host, and methods of making the vectors.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Viral diagnostics
- Vaccine research

Competitive Advantages

- Ease of manufacture
- Multivalent live attenuated vaccines
- B cell and T cell activation
- Low-cost vaccines

Development Stage

- In vivo data assessment (animal)

Inventors: Shirin Munir (NIAID), Linda Brock (NIAID), Ursula Buchholz (NIAID), Peter Collins (NIAID).

Publications: None.

Intellectual Property: HHS Reference No. E–018–2018/0—U.S. Provisional Application No. 62/661,320, filed April 23, 2018 (pending).

Licensing Contact: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Dated: April 26, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–09660 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0289]

Cook Inlet Regional Citizens' Advisory Council (CIRCAC) Recertification

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: This notice informs the public that the Coast Guard has completed its triennial recertification of the Cook Inlet Regional Citizens' Advisory Council (CIRCAC) as an alternative voluntary advisory group for Cook Inlet, Alaska. The certification allows the CIRCAC to monitor the activities of terminal facilities and crude oil tankers under an alternative composition other than prescribed Cook Inlet Program established by statute.

DATES: This recertification is effective for the period from September 1st, 2017, through August 31st, 2018.

FOR FURTHER INFORMATION CONTACT: LT Jonathan Dale, Seventeenth Coast Guard District (dpi), by phone at (907)463–2812, email at *jonathan.dale@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

As part of the Oil Pollution Act of 1990, Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), 33 U.S.C. 2732, to foster a long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and oil tankers.

The President has delegated his authority under 33 U.S.C 2732(o) respecting certification of advisory councils, or groups, subject to the Act to the Secretary of the Department of Homeland Security. Section 8(g) of Executive Order 12777, (56 FR 54757, October 22, 1991), as amended by section 34 of Executive Order 13286 (68 FR 10619, March 5, 2003). The Secretary redelegated that authority to the Commandant of the USCG. Department of Homeland Security Delegation No. 0170.1, paragraph 80 of section II. The Commandant redelegated that authority to the Chief, Office of Marine Safety, Security and Environmental Protection (G–M) on March 19, 1992 (letter #5402).

The Assistant Commandant for Marine Safety and Environmental Protection (G–M), redelegated recertification authority for advisory councils, or groups, to the Commander, Seventeenth Coast Guard District on February 26, 1999 (letter #16450).

On July 7, 1993, the USCG published a policy statement, ''Alternative Voluntary Advisory Groups, Prince William Sound and Cook Inlet'' (58 FR 36504), to clarify the factors considered in making the determination as to whether advisory councils, or groups, should be certified in accordance with the Act.

On September 16, 2002, the USCG published a policy statement, 67 FR 58440, which changed the recertification procedures such that applicants are required to provide the USCG with comprehensive information every three years (triennially). For each of the two years between the triennial application procedures, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification. Further, public comment is only solicited during the triennial comprehensive review.

Discussion of Comments

On June 29th, 2017, the USCG published a ''Notice; request for comments for recertification of Cook Inlet Regional Citizens' Advisory Council'' in the **Federal Register** (82 FR 29572). We received 43 letters commenting on the proposed action. No public meeting was requested. One comment was received questioning CIRCAC's recent changes to its by laws governing the Tourism Group. Through coordination of the involved parties, the Coast Guard is satisfied that the concern

is now resolved. All of the other submissions were positive comments, and supported recertification. These letters consistently cited CIRCAC's broad representation of the respective community's interest, appropriate actions to keep the public informed, improvements to both spill response preparation and spill prevention, and oil spill industry monitoring efforts that combat complacency—as intended by the Act.

Recertification

By letter dated August 22, 2017, the Commander, Seventeenth Coast Guard certified that the CIRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). While the triennial review is valid until August 31, 2020, the annual recertification terminates on August 31, 2018.

April 20, 2018.

Michael F. McAllister,

Rear Admiral, U.S. Coast Guard Commander, Seventeenth Coast Guard District.

[FR Doc. 2018–09664 Filed 5–4–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0027]

Committee Name: Homeland Security Academic Advisory Council

AGENCY: Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee Reestablishment.

SUMMARY: The Secretary of Homeland Security has determined that the reestablishment of the Homeland Security Academic Advisory Council (HSAAC) is necessary and in the public interest in connection with the performance of her duties as Secretary of the U.S. Department of Homeland Security (DHS). This determination follows consultation with the Committee Management Secretariat, General Services Administration.

DATES: Interested persons are invited to submit comments by 15 days after publication of this notice.

ADDRESSES: If you desire to submit comments on this action, they must be submitted within 15 days after publication of Notice. Comments must be identified by Docket Number: DHS–2018–0027 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: AcademicEngagement@hq.dhs.gov.* Include the docket number DHS–2018–0027 in the subject line of the message. Include the docket number in the subject line of the message.
- *Fax:* 202–282–1044. Include ''ATTN: Office of Academic Engagement'' on the cover page of the document.
- *Mail:* Academic Engagement; Office of Academic Engagement/Mailstop 0385, Department of Homeland Security, 245 Murray Lane SW, Washington, DC 20528–0440.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and docket number DHS–2017–0016. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket, to read background documents or comments received by the Homeland Security Academic Advisory Council, go to *http://www.regulations.gov* and search for ''Homeland Security Academic Advisory Council.''

FOR FURTHER INFORMATION CONTACT: Trent Frazier, Office of Academic Engagement/Mailstop 0385, Department of Homeland Security, 245 Murray Lane SW, Washington, DC 20528–0440, email: *AcademicEngagement@hq.dhs.gov,* tel: 202–447–4686 and fax: 202–282–1044.

SUPPLEMENTARY INFORMATION: For the reasons set forth below, the Secretary of Homeland Security has determined that the reestablishment of the HSAAC is necessary and in the public interest. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

The HSAAC is being reestablished in accordance with the provisions of the Federal Advisory Committee Act (FACA) 5 U.S.C. App. (Pub. L. 92–463). The HSAAC will provide advice and recommendations to the Secretary and senior leadership on matters relating to student and recent graduate recruitment; international students; academic research; campus and community resiliency, security and preparedness; faculty exchanges; and cybersecurity.

Balanced Membership Plans: The HSAAC is composed of up to 23 members who are appointed by and serve at the pleasure of the Secretary of Homeland Security. To ensure a diverse, balanced membership on the HSAAC, the members serve as representatives, representing the viewpoints of institutions of higher education, community colleges, elementary and secondary education (K–12), school systems, and/or partnership groups.

Duration: Continuing.

Responsible DHS Official: Trent Frazier, *AcademicEngagement@hq.dhs.gov,* 202–447–4686.

Dated: May 1, 2018.

Trent Frazier,

Executive Director for Academic Engagement.

[FR Doc. 2018–09624 Filed 5–4–18; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: Airport Security Part 1542

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0002, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection includes requirements for airport operators to submit certain information to TSA, as well as to maintain and update records to ensure compliance with security provisions.

DATES: Send your comments by June 6, 2018. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting

comments, of the following collection of information on September 7, 2017, 82 FR 42356.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Title: Airport Security Part 1542.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0002.

Forms(s): NA.

Affected Public: Airport operators.

Abstract: The information collection is used to determine compliance with 49 CFR part 1542 and to ensure passenger safety and security by monitoring airport operator security procedures. The following information collections and other recordkeeping requirements with which respondent covered airport operators must comply fall under this OMB control number: (1) Development of an Airport Security Program (ASP) and submission to TSA; (2) as applicable, development of airport operator requested or TSA-required ASP amendments, submission to TSA, and implementation; (3) collection of data necessary to complete a criminal history records check (CHRC) for those individuals with unescorted access authority to a Security Identification Display Area (SIDA); (4) submission to TSA of identifying information about individuals to whom the airport operator has issued identification media, such as name, address, and country of birth, in order for TSA to conduct a Security Threat Assessment (STA); (5) information collection and recordkeeping requirements associated with airport operator compliance with Security Directives (SDs) issued pursuant to the regulation; and (6) watch list matching of individuals subject to TSA's regulatory requirements against government watch lists.

TSA is revising this information collection by modifying the type of information collected. TSA previously collected information relating to a since-discontinued requirement that airport operators verify the employment histories of certain applicants, TSA has relieved the airport operators of this burden.

Number of Respondents: 438.

Estimated Annual Burden Hours: An estimated 1,786,924 hours annually.[1]

Dated: May 1, 2018.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2018–09626 Filed 5–4–18; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2018–N011; FVHC98210305860–XXX–FF03E14000]

Draft Restoration Plan and Environmental Assessment for the Cardinal Valley Natural Habitat Restoration Project, Oronogo-Duenweg Mining Belt Superfund Site, Missouri

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation and Liability Act and the National Environmental Policy Act, the natural resource Trustees for the Tri-State Mining District (TSMD) site announce the availability for public comment of a Draft Restoration Plan and Environmental Assessment (Draft RP/EA) for TSMD natural resource damage restoration. The Draft RP/EA presents a restoration project the Trustees are proposing to implement to restore natural resources and services injured by hazardous substances released in and around the TSMD site.

DATES: Written comments must be received by June 6, 2018.

ADDRESSES: *Submitting Comments:* Send written comments to one of the following addresses:

- *U.S. mail:* Scott Hamilton; U.S. Fish and Wildlife Service, Missouri Ecological Services Field Office, 101 Park DeVille Dr., Suite A, Columbia, MO 65203; or
- *Email: scott_hamilton@fws.gov;* put ''TSMD RP/EA'' in the email subject line.

Obtaining the Draft Restoration Plan/Environmental Assessment: The Draft RP/EA is available for download from the U.S. Fish and Wildlife Service Midwest Region Natural Resource Damage Assessment website, at: *https://www.fws.gov/midwest/es/ec/nrda/motristate/index.html.*

FOR FURTHER INFORMATION CONTACT: Scott Hamilton, U.S. Fish and Wildlife Service, at 573–234–2132, extension 122 (phone) or *scott_hamilton@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Introduction

The U.S. Department of the Interior (U.S. Fish and Wildlife Service) and the State of Missouri (Missouri Department of Natural Resources) are natural resource trustees (Trustees) for natural resources and services injured by hazardous substances at the Tri-State Mining District (TSMD) site, located in southwest Missouri. The Trustees have prepared a Draft Restoration Plan and Environmental Assessment (Draft RP/EA) to restore injured natural resources and services at the TSMD site pursuant to both the Comprehensive Environmental Response, Compensation and Liability Act natural resource damages assessment and restoration (NRDAR) regulations at 43 CFR part 11 and the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 *et seq.*), and its implementing regulations at 40 CFR parts 1500–1508. NEPA requires Federal agencies to conduct environmental reviews of proposed actions to consider the potential impacts on the environment.

Draft Restoration Plan Alternatives

Consistent with the U.S. Department of the Interior NRDAR regulations and

[1] Since the publication of the 60-day notice, the estimate has been updated from 1,618,268 to 1,786,924 annual burden hours

NEPA, the Trustees evaluated a suite of five alternatives for conducting the type and scale of restoration sufficient to compensate the public for natural resource injuries and service losses. Based on selection factors, including location, technical feasibility, cost effectiveness, provision of natural resource services similar to those lost due to contamination, and net environmental consequences, the Trustees have identified a preferred alternative. Under this preferred alternative, the Trustees would use a combination of biosolids, manure, and woody material to return soil fertility to areas where remedial work removed mine waste and contaminated soil, leaving behind degraded soils and residual metals. Following application of soil amendments, native seed would be applied to the landscape in an attempt to restore prairie habitat and associated natural resource services. Prescribed fire, mowing, and other weed management techniques would be used to maintain desirable habitat conditions. Conservation easements would be placed on restoration parcels, and areas would be managed for wildlife habitat and limited recreation.

Public Comments

Comments are specifically requested regarding the alternatives, proposed restoration techniques and projects, scope of analysis, and assessment of impacts. Please see the **ADDRESSES** section for how to submit information.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority of this action is the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the implementing NRDAR regulations found at 43 CFR part 11.

Dated: February 16, 2018.

Charles Wooley,

Acting Regional Director, Midwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2018–09599 Filed 5–4–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2018–N031; FXES111301 00000C4–189–FF01E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews for 156 Species in Oregon, Washington, Hawaii, Palau, Guam, and the Northern Mariana Islands

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are initiating 5-year status reviews for 156 species in Oregon, Washington, Hawaii, Palau, Guam, and the Northern Mariana Islands under the Endangered Species Act of 1973, as amended (Act). A 5-year review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any new information on these species that has become available since the last review.

DATES: To ensure consideration in our reviews, we are requesting submission of new information no later than July 6, 2018. However, we will continue to accept new information about any species at any time.

ADDRESSES: Submit information on the Hutton tui chub and Nelson's checker-mallow (of Oregon and Washington) via U.S. mail to Field Supervisor, Attention: 5-Year Review, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Ave., Suite 100, Portland, OR 97266.

Submit information on any of the 154 species in Hawaii, Palau, Guam, or the Northern Mariana Islands via U.S. mail to Field Supervisor; Attention: 5-Year Review; U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Blvd., Room 3– 122 Honolulu, HI 96850; or by email to *pifwo_admin@fws.gov.*

FOR FURTHER INFORMATION CONTACT: For Hutton tui chub and Nelson's checker-mallow (of Oregon and Washington), contact Michele Zwartjes, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, at 503–231–6179.

For the 154 species in Hawaii, Palau, Guam, or the Northern Mariana Islands, contact Gregory Koob, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, at 808–792–9400.

Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Why do we conduct 5-year reviews?

Under the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*), we maintain lists of endangered and threatened wildlife and plant species (referred to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for wildlife) and 17.12 (for plants). Section 4(c)(2) of the Act requires us to review each listed species' status at least once every 5 years. For additional information about 5-year reviews, refer to our factsheet at *http://www.fws.gov/endangered/what-we-do/recovery-overview.html.*

What information do we consider in our review?

A 5-year review considers all new information available at the time of the review. In conducting these reviews, we consider the best scientific and commercial data that have become available since the listing determination or most recent status review, such as:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been implemented that benefit the species;

(D) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the Act); and

(E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information will be considered during the 5-year review and will also be useful in evaluating the ongoing recovery programs for these species.

Which species are under review?

This notice announces our active review of the 156 species listed in the table below.

Common name	Scientific name	Status	Known range of species occurrence	Final listing rule and publication date
Animals				
Mammals				
Pacific sheath-tailed bat (Mariana subspecies) (Payeyi, Paischeey).	*Emballonura semicaudata rotensis.*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Mariana fruit bat	*Pteropus mariannus mariannus*	Threatened	Guam, Northern Mariana Islands.	49 FR 33881, 8/27/1984; 70 FR 1190, 1/6/2005.
Little Mariana fruit bat	*Pteropus tokudae*	Endangered	Guam	49 FR 33881, 8/27/1984.
Birds				
Nightingale reed warbler	*Acrocephalus luscinia*	Endangered	Guam, Northern Mariana Islands.	35 FR 8491, 6/2/1970; 35 FR 18319, 12/2/1970.
Mariana gray swiftlet	*Aerodramus vanikorensis bartschi.*	Endangered	Guam, Northern Mariana Islands, Hawaii.	49 FR 33881, 8/27/1984.
Hawaiian crow (Alala)	*Corvus hawaiiensis*	Endangered	Hawaii	32 FR 4001, 3/11/1967.
Mariana crow (Aga)	*Corvus kubaryi*	Endangered	Guam, Northern Mariana Islands.	49 FR 33881, 8/27/1984.
Mariana common moorhen	*Gallinula chloropus guami*	Endangered	Guam, Northern Mariana Islands.	49 FR 33881, 8/27/1984.
Akiapolaau	*Hemignathus wilsoni*	Endangered	Hawaii	32 FR 4001, 3/11/1967.
Palila	*Loxioides bailleui*	Endangered	Hawaii	32 FR 4001, 3/11/1967.
Hawaii akepa	*Loxops coccineus*	Endangered	Hawaii	35 FR 16047, 10/13/1970.
Micronesian megapode	*Megapodius laperouse*	Endangered	Guam, Northern Mariana Islands, Palau.	35 FR 8491, 6/2/1970.
Hawaii creeper	*Oreomystis mana*	Endangered	Hawaii	40 FR 44149, 9/25/1975.
Guam rail	*Rallus owstoni*	Endangered	Guam	49 FR 14354, 4/11/1984; 49 FR 33881, 8/27/1984; 54 FR 43966, 10/30/1989.
Guam kingfisher	*Todiramphus cinnamominus*	Endangered	Guam	49 FR 33881, 8/27/1984; 69 FR 62943, 10/28/2004.
Bridled white-eye	*Zosterops conspicillatus conspicillatus.*	Endangered	Guam	49 FR 33881, 8/27/1984.
Rota bridled white-eye	*Zosterops rotensis*	Endangered	Northern Mariana Islands	69 FR 3022, 1/22/2004.
Reptiles				
Slevin's skink	*Emoia slevini*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Fishes				
Hutton tui chub	*Gila bicolor* ssp.	Threatened	Oregon	50 FR 12302, 3/28/1985.
Snails				
Newcomb's tree snail	*Newcombia cumingi*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Humped tree snail (Akaleha, Denden).	*Partula gibba*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Langford's tree snail (Akaleha, Denden).	*Partula langfordi*	Endangered	Northern Mariana Islands	80 FR 59423, 10/1/2015.
Guam tree snail (Akaleha, Denden).	*Partula radiolata*	Endangered	Guam	80 FR 59423, 10/1/2015.
Lanai tree snail	*Partulina semicarinata*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Lanai tree snail	*Partulina variabilis*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Fragile tree snail (Akaleha dogas, Denden).	*Samoana fragilis*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Crustaceans				
Anchialine pool shrimp	*Procaris hawaiana*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
Anchialine pool shrimp	*Vetericaris chaceorum*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Insects				
Hawaiian picture-wing fly	*Drosophila digressa*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Hawaiian picture-wing fly	*Drosophila heteroneura*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila mulli*	Threatened	Hawaii	71 FR 26835, 5/9/2006.
Hawaiian picture-wing fly	*Drosophila ochrobasis*	Endangered	Hawaii	71 FR 26835, 5/9/2006.
Rota blue damselfly (Dulalas Luta, Dulalas Luuta).	*Ischnura luta*	Endangered	Northern Mariana Islands	80 FR 59423, 10/1/2015.

Common name	Scientific name	Status	Known range of species occurrence	Final listing rule and publication date
Mariana wandering butterfly (Ababbang, Libweibwogh).	*Vagrans egistina*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
		Plants		
		Flowering Plants		
Liliwai	*Acaena exigua*	Endangered	Hawaii	57 FR 20772, 5/15/1992.
No common name	*Achyranthes mutica*	Endangered	Hawaii	61 FR 53108, 10/10/1996.
Round-leaved chaff-flower	*Achyranthes splendens* var. *rotundata*.	Endangered	Hawaii	51 FR 10518, 3/26/1986.
Mauna Loa silversword (Kau).	*Argyroxiphium kauense*	Endangered	Hawaii	58 FR 18029, 4/7/1993.
Ahinahina	*Argyroxiphium sandwicense* ssp. *sandwicense*.	Endangered	Hawaii	51 FR 9814, 3/1/1986.
Kookoolau	*Bidens campylotheca pentamera*.	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Kookoolau	*Bidens campylotheca waihoiensis*.	Endangered	Hawaii	8 FR 32013, 5/28/2013.
Kookoolau	*Bidens conjuncta*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Bidens hillebrandiana* ssp. *hillebrandiana*.	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Kookoolau	*Bidens micrantha ctenophylla*	Endangered	Hawaii	8 FR 64637, 10/29/2013.
Siboyas halumtanu, Siboyan halom tano.	*Bulbophyllum guamense*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Oha wai	*Clermontia drepanomorpha*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Oha wai	*Clermontia lindseyana*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Oha wai	*Clermontia peleana*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Oha wai	*Clermontia pyrularia*	Endangered	Hawaii	9 FR 10305, 3/4/1994.
Haha	*Cyanea asplenifolia*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea copelandii* ssp. *copelandii*.	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Haha	*Cyanea duvalliorum*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea hamatiflora* ssp. *carlsonii*.	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Nui, Haha	*Cyanea horrida*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea kunthiana*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea maritae*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea marksii*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Haha	*Cyanea mauiensis*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea munroi*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea obtusa*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Akuaku	*Cyanea platyphylla*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
No common name	*Cyanea profuga*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea shipmanii*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Popolo	*Cyanea solanacea*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haha	*Cyanea stictophylla*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Haha	*Cyanea tritomantha*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Fadang	*Cycas micronesica*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
No common name	*Cyperus fauriei*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Puukaa	*Cyperus trachysanthos*	Endangered	Hawaii	61 FR 53108, 10/10/1996.
Haiwale	*Cyrtandra ferripilosa*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haiwale	*Cyrtandra filipes*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haiwale	*Cyrtandra giffardii*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
No common name	*Cyrtandra nanawaleensis*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Haiwale	*Cyrtandra oxybapha*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Haiwale	*Cyrtandra tintinnabula*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
No common name	*Cyrtandra wagneri*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
No common name	*Delissea undulata*	Endangered	Hawaii	61 FR 53124, 10/10/1996.
No common name	*Dendrobium guamense*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
No common name	*Eugenia bryanii*	Endangered	Guam	80 FR 59423, 10/1/2015.
No common name	*Festuca molokaiensis*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Nohoanu	*Geranium hanaense*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Nohoanu	*Geranium hillebrandii*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Gouania vitifolia*	Endangered	Hawaii	59 FR 32932, 6/27/1994.
Honohono	*Haplostachys haplostachya*	Endangered	Hawaii	44 FR 62468, 10/30/1979.
Paudedo	*Hedyotis megalantha*	Endangered	Guam	80 FR 59423, 10/1/2015.
Ufa-halomtano	*Heritiera longipetiolata*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
No common name	*Hesperomannia arbuscula*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
Hau kuahiwi	*Hibiscadelphus giffardianus*	Endangered	Hawaii	61 FR 53137, 10/10/1996.

Common name	Scientific name	Status	Known range of species occurrence	Final listing rule and publication date
Hau kuahiwi	*Hibiscadelphus hualalaiensis*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Aupaka	*Isodendrion hosakae*	Endangered	Hawaii	56 FR 1454, 1/14/1991.
Kioele	*Kadua coriacea*	Endangered	Hawaii	57 FR 20772, 5/15/1992.
Kohe malama malama o kanaloa.	*Kanaloa kahoolawensis*	Endangered	Hawaii	64 FR 48307, 9/3/1999.
Koki'o	*Kokia drynarioides*	Endangered	Hawaii	49 FR 47397, 12/4/1984.
No common name	*Lepidium orbiculare*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
No common name	*Lipochaeta venosa*	Endangered	Hawaii	44 FR 62468, 10/30/1979.
No common name	*Maesa walkeri*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Alani	*Melicope zahlbruckneri*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Sea bean	*Mucuna sloanei* var. *persericea*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Kolea	*Myrsine vaccinioides*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Neraudia ovata*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
No common name	*Nervilia jacksoniae*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
No common name	*Nesogenes rotensis*	Endangered	Northern Mariana Islands	69 FR 18499; 04/08/2004.
Aiea	*Nothocestrum breviflorum*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Kului	*Nototrichium humile*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Osmoxylon mariannense*	Endangered	Northern Mariana Islands	69 FR 18499; 04/08/2004.
Ala ala wai nui	*Peperomia subpetiolata*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Phyllanthus saffordii*	Endangered	Guam	80 FR 59423, 10/1/2015.
No common name	*Phyllostegia bracteata*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Phyllostegia floribunda*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
No common name	*Phyllostegia haliakalae*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Phyllostegia helleri*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
No common name	*Phyllostegia pilosa*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Kiponapona	*Phyllostegia racemosa*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
No common name	*Phyllostegia stachyoides*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
No common name	*Phyllostegia velutina*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
No common name	*Phyllostegia warshaueri*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
No common name	*Pittosporum halophilum*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Pittosporum hawaiiense*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Kuahiwi laukahi	*Plantago hawaiensis*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
No common name	*Platydesma remyi*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Hala pepe	*Pleomele fernaldii*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Hala pepe	*Pleomele hawaiiensis*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Poe	*Portulaca sclerocarpa*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Loulu	*Pritchardia lanigera*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Loulu	*Pritchardia maideniana*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
Loulu	*Pritchardia schattaueri*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Aplokating-palaoan	*Psychotria malaspinae*	Endangered	Guam	80 FR 59423, 10/1/2015.
No common name	*Schiedea diffusa* ssp. *macraei*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
Maolioli	*Schiedea hawaiiensis*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
No common name	*Schiedea jacobii*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Schiedea laui*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Schiedea nuttallii*	Endangered	Hawaii	61 FR 53108, 10/10/1996.
No common name	*Schiedea salicaria*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
Hayun lagu, Tronkon guafi	*Serianthes nelsonii*	Endangered	Guam, Northern Mariana Islands.	52 FR 4907; 02/18/1997.
Anunu	*Sicyos albus*	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Nelson's checker-mallow	*Sidalcea nelsoniana*	Threatened	Oregon, Washington	58 FR 8235, 2/12/1993.
No common name	*Silene hawaiiensis*	Threatened	Hawaii	59 FR 10305, 3/4/1994.
Halomtano, Berenghenas	*Solanum guamense*	Endangered	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Popolo ku mai	*Solanum incompletum*	Endangered	Hawaii	59 FR 56333, 10/10/1994.
No common name	*Stenogyne angustifolia* var. *angustifolia.*	Endangered	Hawaii	44 FR 62468, 10/30/1979.
No common name	*Stenogyne cranwelliae*	Endangered	Hawaii	78 FR 64637, 10/29/2013.
No common name	*Stenogyne kaalae* ssp. *sherffii*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
No common name	*Stenogyne kauaulaensis*	Endangered	Hawaii	78 FR 32013, 5/28/2013.
No common name	*Tabernaemontana rotensis*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
No common name	*Tetramolopium arenarium*	Endangered	Hawaii	59 FR 10305, 3/4/1994.
No common name	*Tetramolopium lepidotum* ssp. *lepidotum.*	Endangered	Hawaii	56 FR 55770, 10/29/1991.
No common name	*Tinospora homosepala*	Endangered	Guam	80 FR 59423, 10/1/2015.
No common name	*Tuberolabium guamense*	Threatened	Guam, Northern Mariana Islands.	80 FR 59423, 10/1/2015.
Hawaiian vetch	*Vicia menziesii*	Endangered	Hawaii	43 FR 17910, 4/26/1978.
No common name	*Vigna o-wahuensis*	Endangered	Hawaii	59 FR 56333, 11/10/1994.
No common name	*Wikstroemia skottsbergiana*	Endangered	Hawaii	81 FR 67786, 9/30/2016.
No common name	*Wikstroemia villosa*	Endangered	Hawaii	78 FR 32013, 5/28/2013.

Common name	Scientific name	Status	Known range of species occurrence	Final listing rule and publication date
Ae	*Zanthoxylum dipetalum* var. *tomentosum*.	Endangered	Hawaii	61 FR 53137, 10/10/1996.
Ferns and Allies				
No common name	*Asplenium peruvianum* var. *insulare*.	Endangered	Hawaii	59 FR 49025, 9/26/1994.
No common name	*Diplazium molokaiense*	Endangered	Hawaii	59 FR 49025, 9/26/1994.
Wawaeiole	*Huperzia mannii*	Endangered	Hawaii	57 FR 20772, 5/15/1992.

Request for New Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See What Information Do We Consider in Our Review? for specific criteria. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

If you wish to provide information for any species listed in the table, please submit your comments and materials to the appropriate contact in **ADDRESSES**.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Comments and materials received will be available for public inspection, by appointment, during normal business hours at the offices to which the comments are submitted.

Completed and Active Reviews

A list of all completed and currently active 5-year reviews addressing species for which the Pacific Region of the Service has lead responsibility is available at *http://www.fws.gov/pacific/ecoservices/endangered/recovery/5year.html.*

Authority

This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq*.).

Theresa E. Rabot,

Acting Regional Director, Pacific Region, U.S. Fish and Wildlife Service.

[FR Doc. 2018–09603 Filed 5–4–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2017–N178; FXES11130900000C2–189–FF09E32000]

Endangered and Threatened Wildlife and Plants; 5-Year Status Reviews for 35 Southeastern Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are initiating 5-year status reviews of 35 species under the Endangered Species Act of 1973, as amended. A 5-year review is an assessment of the best scientific and commercial data available at the time of the review. We are requesting submission of information that has become available since the last reviews of these species.

DATES: To allow us adequate time to conduct these reviews, we must receive your comments or information on or before July 6, 2018. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how to submit information and review information that we receive on these species, see Request for New Information under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For species-specific information, see Request for New Information under **SUPPLEMENTARY INFORMATION**.

SUPPLEMENTARY INFORMATION:

Why do we conduct 5-year reviews?

Under the Endangered Species Act of 1973, as amended, (ESA 16 U.S.C. 1531 *et seq*.), we maintain lists of endangered and threatened wildlife and plant species (referred to as the Lists) in title 50 of the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for wildlife) and 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review. For additional information about 5-year reviews, go to *http://www.fws.gov/endangered/what-we-do/recovery-overview.html,* scroll down to ''Learn More about 5-Year Reviews,'' and click on our factsheet.

Species Under Review

This notice announces our active review of 28 species that are currently listed as endangered:

Fish and Wildlife

Ivory-billed woodpecker (*Campephilus principalis*)
Bermuda petrel (=cahow) (*Pterodroma cahow*)
Laurel dace (*Chrosomus saylori*)
Yellowcheek darter (*Etheostoma moorei*)
Watercress darter (*Etheostoma nuchale*)
Smoky madtom (*Noturus baileyi*)
Chucky madtom (*Noturus crypticus*)
Alabama sturgeon (*Scaphirhynchus suttkusi*)
Dromedary pearlymussel (*Dromus dromas*)
Cumberlandian combshell (*Epioblasma brevidens*)
Cracking pearlymussel (*Hemistena lata*)
Alabama lampmussel (*Lampsilis virescens*)
Birdwing pearlymussel (*Lemiox rimosus*)
Alabama pearlshell (*Margaritifera marrianae*)
Fat pocketbook (*Potamilus capax*)
Pale lilliput (*Toxolasma cylindrellus*)
Slender campeloma (*Campeloma decampi*)

Armored snail (*Pyrgulopsis (=Marstonia) pachyta*)

Plants

Arenaria cumberlandensis (Cumberland sandwort)
Astralagus bibullatus (Guthrie's (=Pyne's) ground plum)
Baptisia arachnifera (Hairy rattleweed)
Campanula robinsiae (Brooksville bellflower)
Cyathea dryopteroides (Elfin tree fern)
Harrisia aboriginum (Aboriginal prickly-apple)
Justicia cooleyi (Cooley's water-willow)
Lesquerella perforata (Spring Creek bladderpod)
Nolina brittoniana (Britton's beargrass)
Trillium persistens (Persistent trillium)

This notice announces our active review of 7 species that are currently listed as threatened:

Fish and Wildlife

Eastern indigo snake (*Drymarchon corais couperi*)
Ringed map turtle (=sawback) (*Graptemys oculifera*)
Slackwater darter (*Etheostoma boschungi*)
Yellowfin madtom (*Noturus flavipinnis*)
Pygmy sculpin (*Cottus pygmaeus*)

Plants

Macbridea alba (White birds in a nest)
Scutellaria floridana (Florida skullcap)

What information do we consider in our review?

A 5-year review considers the best scientific and commercial data that have become available since the current listing determination or most recent status review of each species, such as:

A. Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

B. Habitat conditions, including but not limited to amount, distribution, and suitability;

C. Conservation measures that have been implemented to benefit the species;

D. Threat status and trends (see the five factors under the heading How Do We Determine Whether A Species Is Endangered or Threatened?); and

E. Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

We request any new information concerning the status of any of these 35 species. Information submitted should be supported by documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

We have completed 5-year review documents for the majority of our listed species in the Southeast. In many cases, we will only have to update previous 5-year reviews, but we could possibly conduct a species status assessment (SSA) for some species. An SSA is a compilation of the best available information on the species, as well as its ecological needs based on environmental factors. Next, an SSA describes the current condition of the species' habitat and demographics, and the probable explanations for past and ongoing changes in abundance and distribution within the species' range. Last, an SSA forecasts the species' response to probable future scenarios of environmental conditions and conservation efforts. Overall, an SSA uses the conservation biology principles of resiliency, redundancy, and representation (collectively known as the ''3 Rs'') to evaluate the current and future condition of the species. As a result, the SSA characterizes a species' ability to sustain populations in the wild over time based on the best scientific understanding of current and future abundance and distribution within the species' ecological settings.

An SSA is a biological risk assessment to aid decision makers who must use the best available scientific information to make policy decisions under the ESA. The SSA provides decision makers with a scientifically rigorous characterization of a species' status that and the likelihood that the species will sustain populations, along with key uncertainties in that characterization.

Definitions

A. *Species* means any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate which interbreeds when mature.

B. *Endangered* means any species that is in danger of extinction throughout all or a significant portion of its range.

C. *Threatened* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

How do we determine whether a species is endangered or threatened?

Section 4(a)(1) of the ESA requires that we determine whether a species is endangered or threatened based on one or more of the following five factors:

A. The present or threatened destruction, modification, or curtailment of its habitat or range;

B. Overutilization for commercial, recreational, scientific, or educational purposes;

C. Disease or predation;

D. The inadequacy of existing regulatory mechanisms; or

E. Other natural or manmade factors affecting its continued existence.

Request for New Information

To do any of the following, contact the person associated with the species you are interested in below:

A. To get more information on a species;

B. To submit information on a species; or

C. To review information we receive, which will be available for public inspection by appointment, during normal business hours, at the listed addresses.

Fish and Wildlife

- *Ivory-billed woodpecker:* Amy Trahan, by mail at Louisiana Ecological Services Field Office, U.S. Fish and Wildlife Service, 646 Cajundome Blvd., Suite 400, Lafayette, LA 70506; by fax 337–291–3139, by phone at 337–291–3100, or by email at *lafayette@fws.gov.*
- *Cahow (Bermuda petrel):* John Hammond, by mail at the Raleigh Ecological Services Field Office, U.S. Fish and Wildlife Service, 551 Pylon Drive, #F, Raleigh, NC 27606; by fax at 919–856–4556; by phone at 919–856–4520; or by email at *raleigh_es@fws.gov.*
- *Yellowfin madtom, smoky madtom, and laurel dace:* Warren Stiles; and Chucky madtom, Cumberlandian combshell, birdwing pearlymussel, cracking pearlymussel, and dromedary pearlymussel: Stephanie Chance, both by mail at the Tennessee Ecological Services Field Office, U.S. Fish and Wildlife Service, 446 Neal Street, Cookeville, TN 38501; by fax at 931–528–7075; by phone at 931–528–6481; or by email at *cookeville@fws.gov.*
- *Yellowcheek darter:* Chris Davidson, by mail at Arkansas Ecological Services Field Office, U.S. Fish and Wildlife Service, 110 South Amity Road, Suite 300, Conway, AR 72032; by fax at 501–513–4480; by phone at 501–513–4481; or by email at *arkansas-es_recovery@fws.gov.*
- *Ringed map turtle:* Linda Laclaire; fat pocketbook: Paul Hartfield; and slackwater darter, pygmy sculpin, and watercress darter: Daniel Drennen, all three by mail at the Mississippi Ecological Services Field Office, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Jackson, MS

39213; by fax at 601–965–4340; by phone at 601–965–4900; or by email at *Mississippi_field_office@fws.gov.*

• *Alabama sturgeon:* Jennifer Grunewald; Alabama pearlshell: Anthony Ford; Alabama lampmussel, pale lilliput, slender campeloma, and armored snail: Evan Collins, all three by mail at Alabama Ecological Services Field Office, U.S. Fish and Wildlife Service, 1208B Main St., Daphne, AL 36526; by fax at 251–441–6222; by phone at 251–441–5184; or by email at *Alabama@fws.gov.*

• *Eastern indigo snake:* Michele Elmore, by mail at Georgia Ecological Services Field Office, U.S. Fish and Wildlife Service, P.O. Box 52560, Fort Benning, GA 31995; by fax at 706–544–6419; by phone at 706–544–6428; or by email at *georgiaes@fws.gov.*

Plants

• *Cumberland sandwort, Pyne's ground plum, and Spring Creek bladderpod:* Geoff Call, by mail at the Tennessee Ecological Services Field Office, U.S. Fish and Wildlife Service (see contact information above).

• *Hairy rattleweed:* April Punsulan, by mail at Charleston Ecological Services Field Office, U.S. Fish and Wildlife Service, 176 Croghan Spur Road, Suite 200, Charleston, SC 29412; by fax at 843–727–4218; by phone at 843–727–4707; or by email at *charleston_recovery@fws.gov.*

• *Brooksville bellflower, Cooley's water-willow, and Britton's beargrass:* Todd Mecklenborg, by mail at North Florida Ecological Services Field Office, U.S. Fish and Wildlife Service, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256; by fax 904–731–3045, by phone at 904–731–3336, or by email at *northflorida@fws.gov.*

• *Elfin tree fern:* Angel Colon, by mail at the Caribbean Ecological Services Field Office, U.S. Fish and Wildlife Service, Road 301, Km. 5.1, P.O. Box 491, Boquerón, PR 00622; by fax at 787–851–7440; by phone at 787–851–7297; or by email at *caribbean_es@fws.gov.*

• *Aboriginal prickly-apple:* David Bender, by mail at South Florida Ecological Services Field Office, U.S. Fish and Wildlife Service, 1339 20th Street, Vero Beach, FL 32960; by fax 772–562–4288; by phone at 772–562–3909 extension 294; or by email at *SFESO_plant_5-year_reviews@fws.gov.*

• *White birds in a nest and Florida skullcap:* Vivian Negron-Ortiz, by mail at the Panama City Ecological Services Field Office, U.S. Fish and Wildlife Service, 1601 Balboa Ave., Panama City, FL 32405; by fax at 850–769–2177; by phone at 850–769–0552; or by email at *panamacity@fws.gov.*

• *Persistent trillium:* David Caldwell, by mail at Georgia Ecological Services Field Office, U.S. Fish and Wildlife Service (see contact information above).

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that the entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Availability of Status Reviews

All completed status reviews under the ESA are available via the Service website: *https://www.fws.gov/endangered/species/us-species.html.*

Authority

We publish this document under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: March 20, 2018.

Mike Oetker,

Acting Regional Director, Southeast Region.

[FR Doc. 2018–09604 Filed 5–4–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–FIIS–24967; PS.SNELA0076.00.1]

Minor Boundary Revision at Fire Island National Seashore

AGENCY: National Park Service, Interior.

ACTION: Notification of boundary revision.

SUMMARY: The boundary of Fire Island National Seashore is modified to include 0.23 acres of land, more or less. Fee simple interest in the parcel will be donated to the United States from the National Park Foundation. The property is located in Suffolk County, New York, immediately adjacent to the northwestern boundary of the William Floyd Estate on the mainland portion of Fire Island National Seashore.

DATES: The effective date of this boundary revision is May 7, 2018.

ADDRESSES: The map depicting this boundary revision is available for inspection at the following locations: National Park Service, Land Resources Program Center, Northeast Region, 200 Chestnut Street, Philadelphia, PA 19106–2878, and National Park Service, Department of the Interior, 1849 C Street NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Deputy Realty Officer Jennifer Cherry, National Park Service, Land Resources Program Center, Northeast Region, New England Office, 115 John Street, 5th Floor, Lowell, MA 01852, telephone (978) 970–5260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 54 U.S.C. 100506(c), the boundary of Fire Island National Seashore is modified to include one adjoining tract containing 0.23 acres of land, more or less. The boundary revision is depicted on Map No. 615/137,241, dated March 2017.

Specifically, 54 U.S.C. 100506(c) provides that, after notifying the Committee on Natural Resources of the House of Representatives and the Committee on Energy and Natural Resources of the Senate, the Secretary of the Interior is authorized to make this boundary revision upon publication of notice in the **Federal Register**. The Committees have been notified of this boundary revision. This boundary revision and subsequent acquisition will ensure preservation and protection of the Park's historic and natural resources.

Dated: March 5, 2018.

Debbie Conway,

Acting Regional Director, Northeast Region.

[FR Doc. 2018–09583 Filed 5–4–18; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

Public Availability of FY 2016 Service Contracts Inventory Analysis, and Planned Analysis of FY 2017 Service Contracts Inventory

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010, the U.S. International Trade Commission is publishing this notice to advise the public of the availability of the FY 2016 Service Contracts Inventory Analysis, and Planned Analysis of FY 2017 Service Contracts Inventory. The FY 2016 inventory analysis provides information on specific service contract actions that were analyzed as part of the FY 2016 inventory. The 2016 inventory provides information on service contract actions over $25,000, which were made in FY 2016. The inventory information

is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 and December 19, 2011, by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/procurement/memo/service-contract-inventory-guidance.pdf.*

The FY 2017 inventory planned analysis provides information on which functional areas will be reviewed by the agency. The United States International Trade Commission has posted its FY 2016 inventory, FY 2017 planned analysis at the following link: *https://www.usitc.gov/procurement.htm*.

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Debra Bridge, U.S. International Trade Commission, Office of Procurement, 500 E Street SW, Washington, DC 20436; *debra.bridge@usitc.gov;* (202) 205–2004.

By order of the Commission.

Issued: May 2, 2018.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2018–09673 Filed 5–4–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Blood Cholesterol Testing Strips and Associated Systems Containing the Same, DN 3313;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Polymer Technology Systems, Inc. on April 30, 2018. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain blood cholesterol testing strips and associated systems containing the same. The complaint names as respondents: ACON Laboratories, Inc. of San Diego, CA; and ACON Biotech (Hangzhou) Co., Ltd of China. The complainant requests that the Commission issue an exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (Docket No. 3313) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electonic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 1, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–09569 Filed 5–4–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Blow-Molded Bag-In-Container Devices, Associated Components, and End Products Containing or Using Same, DN 3312;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Anheuser-Busch InBev S.A. and Anheuser-Busch, LLC on April 30, 2018. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain blow-molded bag-in-container devices, associated components, and end products containing or using same. The complaint names as respondents: Heineken International B.V. of the Netherlands; Heineken N.V. of the Netherlands; Heineken USA Inc. of White Plains, NY; Heineken Holding N.V. of the Netherlands; Heineken Beer Systems B.V. of the Netherlands; Heineken Brouwerijen B.V. of the Netherlands; Heineken Export Americas B.V. of the Netherlands; and Heineken Global Procurement B.V. of the Netherlands. The complainant requests that the Commission issue an exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3312) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electonic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 1, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–09568 Filed 5–4–18; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJP) Docket No. 1745]

Meeting of the Global Justice Information Sharing Initiative Federal Advisory Committee

AGENCY: Office of Justice Programs (OJP), Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Global Justice Information Sharing Initiative (Global) Federal Advisory Committee (GAC) to discuss the Global Initiative, as described at *www.it.ojp.gov/global.*

DATES: The meeting will take place on Wednesday, August 29, 2018, from 9:00 a.m. to 4:00 p.m. ET.

ADDRESSES: The meeting will take place at the Office of Justice Programs offices (in the Main Conference Room), 810 7th Street, Washington, DC 20531; Phone: (202) 514–2000 [*Note:* this is not a toll-free number].

FOR FURTHER INFORMATION CONTACT: Tracey Trautman, Global Designated Federal Employee (DFE), Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street, Washington, DC 20531; Phone (202) 305–1491 [*Note:* this is not a toll-free number]; Email: *tracey.trautman@ojp.usdoj.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Due to security measures, however, members of the public who wish to attend this meeting must register with Ms. Tracey Trautman at the above address at least (7) days in advance of the meeting. Registrations will be accepted on a space available basis. Access to the meeting will not be allowed without registration. All attendees will be required to sign in at the meeting registration desk. Please bring photo identification and allow extra time prior to the meeting. Anyone requiring special accommodations should notify Ms. Trautman at least seven (7) days in advance of the meeting.

Purpose: The GAC will act as the focal point for justice information systems integration activities in order to facilitate the coordination of technical, funding, and legislative strategies in support of the Administration's justice priorities.

The GAC will guide and monitor the development of the Global information sharing concept. It will advise the Assistant Attorney General, OJP; the Attorney General; the President (through the Attorney General); and local, state, tribal, and federal policymakers in the executive, legislative, and judicial branches. The GAC will also advocate for strategies for accomplishing a Global information sharing capability.

Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the DFE.

Tracey Trautman,

Global DFE, Deputy Director, Bureau of Justice Assistance Office of Justice Programs, U.S. Department of Justice.

[FR Doc. 2018–09420 Filed 5–4–18; 8:45 am]

BILLING CODE 4410–18–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 18–040]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' for approval under the Paperwork Reduction Act (PRA). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection,

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Lori Parker, National Aeronautics and Space Administration, 300 E Street SW, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lori Parker, NASA Clearance Officer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, (202) 358–1351.

SUPPLEMENTARY INFORMATION:

I. Abstract

The proposed information collection activity 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 information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

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. 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.

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 Agency's services will be unavailable.

II. Methods of Collection

The Agency 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;

Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;

Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;

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. 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.

As a general matter, information collections 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.

III. Data

Title: Extension of the Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 2700–0153.

Type of Review: Extension of approval for a collection of information.

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

Average Expected Annual Number of Activities: 60.

Average Number of Respondents per Activity: 300.

Annual Responses: 18,000.

Frequency of Responses: Once per request.

Average Minutes per Response: 5.

Burden Hours: 1,500.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Lori Parker,

NASA PRA Clearance Officer.

[FR Doc. 2018–09672 Filed 5–4–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2018–037]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when agencies no longer need them for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives of the United States and to destroy, after a specified period, records lacking administrative, legal, research, or other value. NARA publishes notice in the **Federal Register** for records schedules in which agencies propose to destroy records they no longer need to conduct agency business. NARA invites public comments on such records schedules.

DATES: NARA must receive requests for copies in writing by June 6, 2018. Once NARA finishes appraising the records, we will send you a copy of the schedule you requested. We usually prepare appraisal memoranda that contain additional information concerning the records covered by a proposed schedule. You may also request these. If you do, we will also provide them once we have completed the appraisal. You have 30 days after we send to you these requested documents in which to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this

notice by contacting Records Appraisal and Agency Assistance (ACRA) using one of the following means:

Mail: NARA (ACRA); 8601 Adelphi Road; College Park, MD 20740–6001.

Email: request.schedule@nara.gov.

FAX: 301–837–3698.

You must cite the control number, which appears in parentheses after the name of the agency that submitted the schedule, and a mailing address. If you would like an appraisal report, please include that in your request.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, by mail at Records Appraisal and Agency Assistance (ACRA); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001, by phone at 301–837–1799, or by email at *request.schedule@nara.gov.*

SUPPLEMENTARY INFORMATION: NARA publishes notice in the **Federal Register** for records schedules they no longer need to conduct agency business. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

Each year, Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing records retention periods and submit these schedules for NARA's approval. These schedules provide for timely transfer into the National Archives of historically valuable records and authorize the agency to dispose of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless otherwise specified. An item in a schedule is media neutral when an agency may apply the disposition instructions to records regardless of the medium in which it creates or maintains the records. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is expressly limited to a specific medium. (See 36 CFR 1225.12(e).)

Agencies may not destroy Federal records without Archivist of the United States' approval. The Archivist approves destruction only after thoroughly considering the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value.

In addition to identifying the Federal agencies and any subdivisions requesting disposition authority, this notice lists the organizational unit(s) accumulating the records (or notes that the schedule has agency-wide applicability when schedules cover records that may be accumulated throughout an agency); provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction); and includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it also includes information about the records. You may request additional information about the disposition process at the addresses above.

Schedules Pending

1. Department of Agriculture, Foreign Agricultural Service (DAA–0166–2018–0005, 2 items, 2 temporary items). Agricultural Attachés records documenting visitors programs, agency sponsored public representation functions, staffing information, and administrative records pertaining to established attaché posts.

2. Department of Agriculture, Foreign Agricultural Service (DAA–0166–2018–0015, 3 items, 3 temporary items). Budget records documenting budget formulation, estimates, and enactment. Information includes projections, allowances, preparation papers, justification statements, and supporting documentation.

3. Department of Agriculture, Foreign Agricultural Service (DAA–0166–2018–0017, 2 items, 2 temporary items). Agricultural import records documenting sugar and dairy import assistance to developing countries. Information includes applications, agreements, and related background information for participants in the two programs.

4. Department of Homeland Security, United States Citizenship and Immigration Services (DAA–0566–2018–0001, 2 items, 2 temporary items). Records of the Outstanding American by Choice initiative, which includes case files related to recognizing the contributions and achievements of individual naturalized U.S. citizens.

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2018–09629 Filed 5–4–18; 8:45 am]

BILLING CODE 7515–01–P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy

Designation of Three High Intensity Drug Trafficking Areas

AGENCY: Office of National Drug Control Policy, Executive Office of the President.

ACTION: Notice of HIDTA designations.

SUMMARY: The Director of the Office of National Drug Control Policy designated three areas as High Intensity Drug Trafficking Areas (HIDTA) pursuant to 21 U.S.C. 1706. These areas are the First, Third, and Fourth Judicial Districts of Alaska.

FOR FURTHER INFORMATION CONTACT: Questions regarding this notice should be directed to Michael K. Gottlieb, National HIDTA Program Director, Office of National Drug Control Policy, Executive Office of the President, Washington, DC 20503; (202) 395–4868.

Dated: May 1, 2018.

Michael J. Passante,

Acting General Counsel.

[FR Doc. 2018–09567 Filed 5–4–18; 8:45 am]

BILLING CODE 3280–F5–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 16 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate:

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Sherry P. Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of July 5, 2016, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The upcoming meetings are:

Dance (review of applications): This meeting will be closed.

Date and time: June 4, 2018; 12:00 p.m. to 2:00 p.m.

Dance (review of applications): This meeting will be closed.

Date and time: June 4, 2018; 3:00 p.m. to 5:00 p.m.

Dance (review of applications): This meeting will be closed.

Date and time: June 5, 2018; 12:00 p.m. to 2:00 p.m.

Opera (review of applications): This meeting will be closed.

Date and time: June 6, 2018; 1:00 p.m. to 3:00 p.m.

Opera (review of applications): This meeting will be closed.

Date and time: June 7, 2018; 1:00 p.m. to 3:00 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: June 12, 2018; 1:30 p.m. to 3:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: June 14, 2018; 1:30 p.m. to 3:30 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: June 18, 2018; 1:00 p.m. to 3:00 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: June 19, 2018; 1:00 p.m. to 3:00 p.m.

Design (review of applications): This meeting will be closed.

Date and time: June 19, 2018; 1130 a.m. to 1:30 p.m.

Design (review of applications): This meeting will be closed.

Date and time: June 19, 2018; 2:30 p.m. to 4:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: June 20, 2018; 1:30 p.m. to 3:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: June 20, 2018; 11:30 a.m. to 1:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: June 20, 2018; 2:30 p.m. to 4:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: June 21, 2018; 11:30 a.m. to 1:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: June 21, 2018; 2:30 p.m. to 4:30 p.m.

Dated: May 1, 2018.

Sherry Hale,

Staff Assistant, National Endowment for the Arts.

[FR Doc. 2018–09554 Filed 5–4–18; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION OF THE ARTS AND THE HUMANITIES

Sunshine Act Meeting; National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), NFAH.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the agenda of the forthcoming meeting of the National Museum and Library Services Board. This notice also describes the function of the Board. Notice of the meeting is required under the Sunshine in Government Act.

DATES: Wednesday, May 23, 2018 from 9:00 a.m. to 12:30 p.m. and 1:30 p.m. to 3:00 p.m. EST

ADDRESSES: The meeting will be held at the IMLS Offices, Panel Room, Suite 4000, 955 L'Enfant Plaza North SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Katherine Maas, Program Specialist, Institute of Museum and Library Services, Suite 4000, 955 L'Enfant Plaza North SW, Washington, DC 20024. Telephone: (202) 653–4798.

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board, which advises the Director of the Institute of Museum and Library Services on general policies with respect to the duties, powers, and authority of the Institute relating to museum, library and information services, will meet on May 23, 2018. The Thirty-Seventh Meeting on Wednesday, May 23, 2018 from 9:00 a.m. to 12:30 p.m., is open to the public. The Executive Session, which will be held from 1:30–3:00 p.m., will be closed pursuant to subsections (c)(4) and (c)(9) of section 552b of Title 5, United States Code because the Board will consider information that may disclose: Trade secrets and commercial or financial information obtained from a person and privileged or confidential; and information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action.

If you need special accommodations due to a disability, please contact: Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024, Telephone: (202) 653–4796, at least seven (7) days prior to the meeting date.

Agenda

Thirty-Seventh Meeting of the National Museum and Library Service Board Meeting:

9:00 a.m.–12:30 p.m. Thirty-Seventh Meeting of the National Museum and Library Service Board Meeting:

I. Welcome and Director's Report
II. Approval of Minutes
III. Guest Speaker: Mayor Stephen K. Benjamin, Vice President, United States Conference of Mayors
IV. Financial and Operations Report
V. Office of Museum Services Report
VI. Office of Library Services Report
VII. Office of Digital and Information Strategy Report
VIII. Quest Speaker: Dr. Kathleen Annette, President, Blandin Foundation: Community Leadership Capacity-Building for Rural and Tribal
IX. Adjourn

(Open to the Public)

1:30 p.m. to 3:00 p.m. Executive Session

(Closed to the Public)

Dated: May 1, 2018.

Danette Hensley,

Office of the General Counsel.

[FR Doc. 2018–09578 Filed 5–3–18; 11:15 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee: Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–

463, as amended), the National Science Foundation (NSF) announces the following meeting:

NAME AND COMMITTEE CODE: Astronomy and Astrophysics Advisory Committee (#13883) (Teleconference).

DATE AND TIME: June 27, 2018; 12:00 p.m.–4:00 p.m.

PLACE: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, Room W2180 (Teleconference).

TYPE OF MEETING: Open.

Attendance information for the meeting will be forthcoming on the website: *https://www.nsf.gov/mps/ast/aaac.jsp.*

CONTACT PERSON: Dr. Christopher Davis, Program Director, Division of Astronomical Sciences, Suite W 9136, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–4910.

PURPOSE OF MEETING: To provide advice and recommendations to the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA) and the U.S. Department of Energy (DOE) on issues within the field of astronomy and astrophysics that are of mutual interest and concern to the agencies.

AGENDA: To provide updates on Agency activities.

Dated: May 2, 2018.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2018–09590 Filed 5–4–18; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of a revision to an announcement of meetings for the transaction of National Science Board business.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 83 FR 18351–53, published on April 26, 2018.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETINGS:

Committee on Awards and Facilities (A&F)

Wednesday, May 2, 2018

Closed session: 2:00–4:00 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Action Item: Ocean Observatories Initiative (OOI) Operations and Management
- Information Item: Geodesy Advancing Geosciences (GAGE) Facility and the Seismological Facilities for the Advancement of Geosciences (SAGE)
- Action Item: Laser Interferometer Gravitational-Wave Observatory (LIGO) Operations and Maintenance
- Information Item: Candidate MREFC-funded Upgrades of the ATLAS and CMS Detectors at the Large Hadron Collider

CHANGES IN THE MEETINGS:

Wednesday, May 2, 2018

Closed session: 2:00–4:00 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Action Item: Ocean Observatories Initiative (OOI) Operations and Management
- Information Item: Geodesy Advancing Geosciences (GAGE) Facility and the Seismological Facilities for the Advancement of Geosciences (SAGE)

Thursday, May 3, 2018

Closed session: 8:00–8:30 a.m.

- Action Item: Laser Interferometer Gravitational-Wave Observatory (LIGO) Operations and Maintenance
- Information Item: Candidate MREFC-funded Upgrades of the ATLAS and CMS Detectors at the Large Hadron Collider

CONTACT PERSON FOR MORE INFORMATION: Brad Gutierrez, *bgutierr@nsf.gov,* 703/292–7000. Please refer to the National Science Board website for additional information. Meeting information and schedule updates (time, place, subject matter, and status of meeting) may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

Chris Blair,

Executive Assistant, National Science Board Office.

[FR Doc. 2018–09751 Filed 5–3–18; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0001]

Sunshine Act Meeting Notice

DATE: Weeks of May 7, 14, 21, 28, June 4, 11, 2018.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of May 7, 2018

Thursday, May 10, 2018

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

2:00 p.m. Briefing on Security Issues (Closed Ex. 1)

Week of May 14, 2018—Tentative

There are no meetings scheduled for the week of May 14, 2018.

Week of May 21, 2018—Tentative

There are no meetings scheduled for the week of May 21, 2018.

Week of May 28, 2018—Tentative

There are no meetings scheduled for the week of May 28, 2018.

Week of June 4, 2018—Tentative

Wednesday, June 6, 2018

2:00 p.m. Briefing on Human Capital and Equal Employment Opportunity (Public Meeting) (Contact: Sally Wilding: 301–287–0596)

Week of June 11, 2018—Tentative

There are no meetings scheduled for the week of June 11, 2018.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the

Secretary, Washington, DC 20555 (301–415–1969), or you may email *Patricia.Jimenez@nrc.gov or Wendy.Moore@nrc.gov.*

Dated: May 3, 2018.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2018–09826 Filed 5–3–18; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0006]

Information Collection: 10 CFR Part 95, Facility Security Clearance and Safeguarding of National Security Information and Restricted Data

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''10 CFR part 95, Facility Security Clearance and Safeguarding of National Security Information and Restricted Data.''

DATES: Submit comments by July 6, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

• *Federal Rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0006. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* David C. Cullison, Office of the Chief Information Officer, Mail Stop: T–2 F43, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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: David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0006 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0006. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0006 on this website.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then 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 supporting statement is available in ADAMS under Accession No. ML17311A846.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David C. Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

Please include Docket ID NRC–2018–0006 in the subject line of your comment submission in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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

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

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* 10 CFR part 95, ''Facility Security Clearance and Safeguarding of National Security Information and Restricted Data''.

2. *OMB approval number:* 3150–0047.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NA.

5. *How often the collection is required or requested:* On occasion and every 5 years.

6. *Who will be required or asked to respond:* NRC-regulated facilities and their contractors who require access to, and possession of NRC classified information.

7. *The estimated number of annual responses:* 340.

8. *The estimated number of annual respondents:* 189.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 503.

10. *Abstract:* The NRC-regulated facilities and their contractors who are authorized to access and possess classified matter are required to provide information and maintain records to ensure an adequate level of protection is provided to NRC classified information and material.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 1st day of May, 2018.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–09555 Filed 5–4–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0089]

Acceptance Sampling Procedures for Exempted and Generally Licensed Items Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 6.6, ''Acceptance Sampling Procedures for Exempted and Generally Licensed Items Containing Byproduct Material.'' RG 6.6 is being withdrawn because the NRC amended its regulations regarding acceptance sampling procedures for exempted and generally licensed items containing byproduct material.

DATES: The effective date of the withdrawal of RG 6.6 is May 7, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0089 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking website*: Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0089. Address questions about NRC dockets 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 NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then 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 basis for withdrawal is located at ADAMS Accession No. ML18057A304.

• *NRC's PDR*: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Harriet Karagiannis, Office of Nuclear Regulatory Research, telephone: 301–415–2493: email: *Harriet.Karagiannis@nrc.gov* or Richard Struckmeyer, Office of Nuclear Material Safety and Safeguards, telephone: (301) 415–5477: email: *Richard.Struckmeyer@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Background

Regulatory Guide 6.6 was published in June 1974 to provide guidance on meeting the requirements in § 32.110 of title 10 of the *Code of Federal Regulations* (10 CFR). The RG 6.6 describes a prescriptive methodology for determining whether a product should be accepted or rejected based on statistical sampling methods. The NRC is withdrawing RG 6.6 because in 2012, the regulations in part 32 of 10 CFR were amended to remove § 32.110 of 10 CFR (77 FR 43673; July 25, 2012). The amendment occurred because the Commission determined that the requirements for manufacturers or initial distributors of exempt and generally licensed products were in some cases overly prescriptive, particularly in the areas of prototype testing and acceptance sampling/quality control procedures. The new rule was intended to focus the regulations on performance rather than procedures. Therefore, the guidance contained in RG 6.6 became obsolete and RG 6.6 needs to be withdrawn.

II. General Considerations

The NRC is withdrawing RG 6.6 because it is no longer needed. Withdrawal of an RG means that the guide no longer provides useful information or has been superseded by other guidance, technological innovations, Congressional actions, or other events. The withdrawal of RG 6.6 does not alter any prior or existing NRC licensing approval or the acceptability of licensee commitments to RG 6.6. Although RG 6.6 is withdrawn, current licensees may continue to use it, and withdrawal does not affect any existing licenses or agreements. However, RG. 6.6 should not be used in future requests or applications for NRC licensing actions.

Dated at Rockville, Maryland, this 1st day of May, 2018.

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. 2018–09591 Filed 5–4–18; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83146; File No. SR–CboeBZX–2018–029]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Allow the Horizons Cadence Hedged U.S. Dividend Yield ETF, a Series of the Horizons ETF Trust I, To Hold Listed Options Contracts in a Manner That Does Not Comply With Rule 14.11(i), Managed Fund Shares

May 1, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 17, 2018, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to allow the Horizons Cadence Hedged US Dividend Yield ETF (the ''Fund''), a series of the Horizons ETF Trust I (the ''Trust''), to hold listed options contracts in a manner that does not comply with Rule 14.11(i) (''Managed Fund Shares''). The shares of the Fund are referred to herein as the ''Shares.''

The text of the proposed rule change is available at the Exchange's website at *www.markets.cboe.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Fund is currently listed on the Exchange pursuant to the generic listing standards under Rule 14.11(i) governing Managed Fund Shares.[5] The Exchange proposes to continue listing and trading the Shares. The Shares would continue to comply with all of the generic listing standards with the exception of the requirement of Rule 14.11(i)(4)(C)(iv)(b) that prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures) (the ''30% Restriction'').[6] [7]

The Shares are offered by the Trust, which was established as a Delaware statutory trust on May 17, 2012. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N–1A with the Commission.[8] The Fund's adviser, Horizons ETFs Management (US) LLC (the ''Adviser''), is not registered as a broker-dealer, but is affiliated with two broker-dealers. The Adviser represents that a fire wall exists and will be maintained between the respective personnel at the Adviser and affiliated broker-dealers with respect to access to information concerning the composition and/or changes to the Fund's portfolio. Personnel who make decisions on the Fund's portfolio composition are currently and shall continue to be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio. The Fund's sub-adviser, Cadence Capital Management LLC (the ''Sub-Adviser''), is not registered as a broker-dealer and is not affiliated with a broker-dealer. Sub-Adviser personnel who make decisions on the Fund's portfolio composition are currently and shall continue to be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio. In the event that (a) the Adviser or Sub-Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer; or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer; the Adviser, Sub-Adviser, or such new adviser or sub-adviser will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the Fund's portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

The Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code of 1986, as amended.

Horizons Cadence Hedged US Dividend Yield ETF

The Fund seeks income and long-term growth of capital. In order to achieve its investment objective, under Normal Market Conditions,[9] the Fund will invest at least 80% of its assets in equity securities of U.S. exchange-listed companies that pay regular dividends (''U.S. Equities''). The Fund's holdings in U.S. Equities currently meet and will continue to meet the generic listing standards for U.S. Component Stocks in Rule 14.11(i)(4)(C)(i)(a). The Fund has the ability to buy and sell call and put options on the S&P 500 Index (''S&P 500 Index Options''). The S&P 500 Index is the index most correlated to the Fund's underlying equity holdings. The options overlay seeks to potentially provide a measure of downside protection and an additional component to the Fund's risk management. The options overlay is actively managed by the Adviser and will adapt to both changing market environments and shifts in the underlying equity holdings of the Fund, but is currently limited by the requirement under Rule 14.11(i)(4)(C)(iv)(b) that prevents the aggregate gross notional exposure of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures).

As noted above, Rule 14.11(i)(4)(C)(iv)(b) prevents the Fund from holding listed derivatives based on

[5] The Commission originally approved BZX Rule 14.11(i) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018) and subsequently approved generic listing standards for Managed Fund Shares under Rule 14.11(i) in Securities Exchange Act Release No. 78396 (July 22, 2016), 81 FR 49698 (July 28, 2016) (SR–BATS–2015–100).

[6] Rule 14.11(i)(4)(C)(iv)(b) provides that ''the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional exposures).'' The Exchange is proposing that the Fund be exempt only from the requirement of Rule 14.11(i)(4)(C)(iv)(b) that prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures). The Fund will meet the requirement that the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures).

[7] The Exchange notes that this proposal is very similar to a previously approved proposal to list and trade a series of Managed Fund Shares on the Exchange with similar exposures to a single underlying reference asset and U.S. exchange-listed equity securities. *See* Securities Exchange Act Release No. 80529 (April 26, 2017), 82 FR 20506 (May 2, 2017) (SR–BatsBZX–2017–14).

[8] The Trust filed a post-effective amendment to the Registration Statement on February 9, 2018 (the ''Registration Statement''). *See* Registration Statement on Form N–1A for the Trust (File Nos. 333–183155 and 811–22732). The descriptions of the Fund and the Shares contained herein are based, in part, on information included in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Trust and affiliated persons under the Investment Company Act of 1940 (15 U.S.C. 80a-1). *See* Investment Company Act Release No. 30695 (September 24, 2013) (File No. 812–14178).

[9] The term ''Normal Market Conditions'' includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or system failures; or force majeure type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

any single underlying reference asset in excess of 30% of the weight of its portfolio (including gross notional exposures). As proposed, the Fund would hold up to 50% of the weight of its portfolio (including gross notional exposures) in S&P 500 Index Options, which are traded on Cboe Exchange, Inc. (''Cboe Options'').[10] The Fund will utilize S&P 500 Index Options to create a collar strategy through selling call options and buying protective put options. This may serve as a buffer to market selloffs, which may lower the volatility of the portfolio. Greater exposure to the S&P 500 through the options would allow the Fund the flexibility to fully implement its risk mitigation strategy. The Exchange notes that the Fund may also hold cash and Cash Equivalents [11] in compliance with Rule 14.11(i)(4)(C)(iii).

As noted above, the Fund's investment in U.S. Equities under Normal Market Conditions constitutes at least 80% of the Fund's assets and such holdings will meet the requirements for U.S. Component Stocks in Rule 14.11(i)(4)(C)(i)(a). In addition to such U.S. Equities holdings, the Fund may hold up to 20% of its assets in cash, Cash Equivalents, and the value of S&P 500 Index Options positions under Normal Market Conditions. The combination of U.S. Equities, cash, Cash Equivalents, and the cash value of S&P 500 Index Options will constitute the entirety of the Fund's holdings and the cash value of these holdings will be used to form the basis for these calculations. The Exchange notes that this is different than the calculation used to measure the Fund's holdings in S&P 500 Index Options as it relates to the Fund holding up to 50% of the weight of its portfolio, which, as noted above, is calculated using gross notional exposures gained through the S&P 500 Index Options in both the numerator and denominator, which is consistent with the derivatives exposure calculation under Rule 14.11(i)(4)(C)(iv). The Exchange represents that, except for the 30% Restriction in Rule 14.11(i)(4)(C)(iv)(b), the Fund's investments will continue to satisfy all of the generic listing standards under BZX Rule 14.11(i)(4)(C) and all other applicable requirements for Managed Fund Shares under Rule 14.11(i).

The Trust is required to comply with Rule 10A–3 under the Act for the initial and continued listing of the Shares of the Fund. In addition, the Exchange represents that the Shares of the Fund will continue to comply with all other requirements applicable to Managed Fund Shares, which include the dissemination of key information such as the Disclosed Portfolio,[12] Net Asset Value,[13] and the Intraday Indicative Value,[14] suspension of trading or removal,[15] trading halts,[16] surveillance,[17] minimum price variation for quoting and order entry,[18] the information circular,[19] and firewalls [20] as set forth in Exchange rules applicable to Managed Fund Shares and the orders approving such rules. Moreover, all of the U.S. Equities and S&P 500 Index Options held by the Fund will trade on markets that are a member of Intermarket Surveillance Group (''ISG'') or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[21] All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of reference asset and intraday indicative values (as applicable), or the applicability of Exchange listing rules specified in this filing shall constitute continued listing requirements for the Shares. The Fund has represented to the Exchange that it will advise the Exchange of any failure by the Fund or Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. FINRA conducts certain cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures with respect to such Fund under Exchange Rule 14.12.

Availability of Information

As noted above, the Fund will comply with the requirements under the Rule 14.11(i) related to Disclosed Portfolio, NAV, and the intraday indicative value. Additionally, the intra-day, closing and settlement prices of exchange-traded portfolio assets, specifically the U.S. Equities and S&P 500 Index Options, will be readily available from the exchanges trading such securities or derivatives, as the case may be, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. Quotation and last sale information for S&P 500 Index Options will be available via the Options Price Reporting Authority. Price information for Cash Equivalents will be available from major market data vendors. The Disclosed Portfolio will be available on the Fund's website (*www.horizonsetfs.com*) free of charge. The Fund's website will include a form of the prospectus for the Fund and additional information related to NAV and other applicable quantitative information. Information regarding market price and trading volume of the Shares will be continuously available throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume for the Shares will be published daily in the financial section of newspapers. Trading in the Shares may be halted for market conditions or for reasons that, in the view of the Exchange, make trading inadvisable. The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange has appropriate rules to facilitate trading in the Shares during all trading sessions. The Exchange prohibits the distribution of material non-public information by

[10] The Commission has previously approved a series of Managed Fund Shares that can hold up to 60% of the weight of its portfolio in listed derivatives based on the S&P 500 Index as the only underlying reference asset. *See* Securities Exchange Act Release No. 82906 (March 20, 2018), 83 FR 12992 (March 26, 2018) (SR–CboeBZX–2017–012) (order approving the listing and trading of the LHA Market State Tactical U.S. Equity ETF).

[11] As defined in Exchange Rule 14.11(i)(4)(C)(iii)(b), Cash Equivalents are short-term instruments with maturities of less than three months, which includes only the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

[12] *See* Rule 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[13] *See* Rule 14.11(i)(4)(A)(ii).

[14] *See* Rule 14.11(i)(4)(B)(i).

[15] *See* Rule 14.11(i)(4)(B)(iii).

[16] *See* Rule 14.11(i)(4)(B)(iv).

[17] *See* Rule 14.11(i)(2)(C).

[18] *See* Rule 14.11(i)(2)(B).

[19] *See* Rule 14.11(i)(6).

[20] *See* Rule 14.11(i)(7).

[21] For a list of the current members of ISG, *see www.isgportal.com*. The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

its employees. Quotation and last sale information for the Shares and U.S. Equities will be available via the CTA high-speed line.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [22] in general and Section 6(b)(5) of the Act [23] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest in that the Shares will meet each of the continued listing criteria in BZX Rule 14.11(i) with the exception of the 30% Restriction in Rule 14.11(i)(4)(C)(iv)(b), which requires that the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional exposures).[24] The Exchange believes that the liquidity in the S&P 500 Index Options markets mitigates the concerns that Rule 14.11(i)(4)(C)(iv)(b) is intended to address and that such liquidity would prevent the Shares from being susceptible to manipulation.[25] Further, allowing the Fund to hold a greater portion of its portfolio in S&P 500 Index Options would mean that the Fund would not be required to use over-the-counter (''OTC'') derivatives if the Adviser deemed it necessary to get exposure in excess of the 30% Restriction in Rule 14.11(i)(4)(C)(iv)(b), which would reduce the Fund's operational burden by allowing the Fund to use listed options contracts to achieve its investment objective and would eliminate the counter-party risk associated with holding OTC derivative instruments. The Exchange further believes that the diversity, liquidity, and market cap of the securities underlying the S&P 500 Index are sufficient to protect against market manipulation of both the Fund's holdings and the Shares as it relates to the S&P 500 Index Options holdings.

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. All of the U.S. Equities and S&P 500 Index Options contracts held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange may obtain information regarding trading in the Shares, U.S. Equities, and the S&P 500 Index Options held by the Fund via the ISG from other exchanges who are a member of ISG or affiliated with a member of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[26] The Exchange further notes that the Fund will meet and be subject to all other requirements of the generic listing rules and other applicable continued listing requirements for Managed Fund Shares under Rule 14.11(i), including those requirements regarding the dissemination of key information such as the Disclosed Portfolio, Net Asset Value, and the Intraday Indicative Value, suspension of trading or removal, trading halts, surveillance, minimum price variation for quoting and order entry, the information circular, and firewalls as set forth in Exchange rules applicable to Managed Fund Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the options strategy of an actively-managed exchange-traded product that will allow the Fund to better compete in the marketplace, thus enhancing competition among both market participants and listing venues, to the benefit of investors and the marketplace.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [27] and Rule 19b–4(f)(6) thereunder.[28]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [29] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [30] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Commission notes that waiver of the operative delay would allow the Fund to hold up to 50% of the weight of its portfolio (including gross notional exposures) in S&P 500 Index Options without delay, and thus allow the Fund to fully implement its risk mitigation strategy without delay. The Commission notes that, other than the 30% Restriction with respect to S&P 500 Index Options, the Fund would continue to satisfy all of the generic listing standards under BZX Rule 14.11(i)(4)(C) and all other requirements applicable to Managed Fund Shares. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] As noted above, the Exchange is proposing that the Fund be exempt only from the 30% Restriction of Rule 14.11(i)(4)(C)(iv)(b) that prevents the aggregate gross notional value of listed derivatives based on any single underlying reference asset from exceeding 30% of the weight of the portfolio (including gross notional exposures). The Fund will continue to meet the requirement that the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures).

[25] In February 2018, the total notional volume traded was approximately $9.4 trillion in S&P 500 Index Options.

[26] *See* note 21, supra.

[27] 15 U.S.C. 78s(b)(3)(A).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[29] 17 CFR 240.19b–4(f)(6).

[30] 17 CFR 240.19b–4(f)(6)(iii).

Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[31]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2018–029 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR-CboeBZX–2018–029. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2018–029 and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09576 Filed 5–4–18; 8:45 am]

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[31] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83144; File No. SR–ISE–2018–38]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add Pricing for P.M. Settled Options on Broad-Based Indexes With Nonstandard Expiration Dates

May 1, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 17, 2018, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Schedule of Fees to add pricing for P.M. settled options on broad-based indexes with nonstandard expiration dates, as described further below.

The text of the proposed rule change is available on the Exchange's website at *http://ise.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange recently received approval to list P.M. settled options on broad-based indexes with nonstandard expiration dates on a twelve month pilot basis, beginning on February 1, 2018.[3] This pilot permits both Weekly Expirations and End of Month expirations similar to those of A.M. settled broad-based index options, except that the exercise settlement value will be based on the index value derived from the closing prices of component stocks.[4] The Exchange proposes to list these aforementioned options, commencing on April 19, 2018, with the symbol ''NDXP.''

The Exchange now proposes to adopt the index pricing applicable to NDX[5] today to NDXP. Accordingly, the Exchange proposes to add the following definition in its Schedule of Fees: '''NDX' will mean A.M. or P.M settled options on the full value of the Nasdaq 100® Index.'' Therefore, each reference to NDX pricing currently in the Schedule of Fees will likewise apply to NDXP under this proposal, as further discussed below. The Exchange initially filed the proposed pricing changes on April 9, 2018 (SR–ISE–2018–33). On April 17, 2018, the Exchange withdrew that filing and submitted this filing.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 82612 (February 1, 2018), 83 FR 5470 (February 7, 2018) (SR–ISE–2017–111).

[4] *Id.*

[5] NDX represents A.M. settled options on the full value of the Nasdaq 100® Index and is traded under the symbol NDX.

Section I: Transaction Fees for Index Options

Today, the Exchange charges a uniform transaction fee of $0.75 per contract for Non-Priority Customer [6] orders in NDX. These fees are assessed to all executions in NDX, including Non-Priority Customer Crossing Orders [7] in NDX. No transaction fee is assessed to Priority Customer [8] orders in NDX. The Exchange now proposes to apply these transaction fees to NDXP.

Section II: Priority Customer Complex Rebates

Today, the tiered Priority Customer Complex Rebates in Section II of the Schedule of Fees are not paid for NDX. As proposed, the Priority Customer Complex Rebates will likewise not be paid for NDXP.

Section IV.C: Non-Priority Customer License Surcharge

Today, the Exchange charges a $0.25 per contract license surcharge for all Non-Priority Customer orders in NDX, which applies to all executions in NDX, including executions of NDX orders that are routed to away markets in connection with the Options Order Protection and Locked/Crossed Market Plan (the ''Plan'').[9] The Exchange currently assesses a $0.25 per contract license surcharge as well as a route-out fee of $0.95 per contract for those Non-Priority Customer NDX orders that are executed on an away market in connection with the Plan. Under the Exchange's proposal, the $0.25 per contract Non-Priority Customer license surcharge for NDX will likewise apply to all executions in NDXP, including executions of NDXP orders that are routed to away markets in connection the Plan. For those NDXP orders that are routed away, the Exchange will also charge the $0.95 per contract route-out fee in addition to the $0.25 per contract license surcharge under this proposal.[10]

Section IV.E: Marketing Fee

By way of background, the Exchange administers a marketing fee program that helps Market Makers (*i.e.,* Primary Market Makers and Competitive Market Makers) establish marketing fee arrangements with Electronic Access Members (''EAMs'') in exchange for those EAMs routing some or all of their order flow to the Market Maker. This program is funded through a fee of $0.70 per contract, which is paid by Market Makers for each regular Priority Customer contract executed in Non-Select Symbols. This fee is currently waived for NDX orders. As proposed, the marketing fee will similarly be waived for NDXP orders.

Section IV.H: Crossing Fee Cap

Today, the Exchange caps Crossing Order fees at $90,000 per month per member on all Firm Proprietary and Non-Nasdaq ISE Market Maker transactions that are part of the originating or contra side of a Crossing Order. Surcharge fees charged by the Exchange for licensed products (*e.g.,* the $0.25 per contract license surcharge for NDX) and the fees for index options as set forth in Section I (*e.g.,* the $0.75 per contract fees for NDX) are currently excluded from the calculation of this monthly fee cap. As proposed, the license surcharge and fees for NDXP will likewise be excluded from the calculation of the monthly Crossing Fee Cap.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In general, the Exchange believes that its proposal is reasonable, equitable and not unfairly discriminatory because NDX and NDXP represent similar options on the same underlying Nasdaq 100® Index and the Exchange therefore desires to apply pricing for NDXP in a similar manner as NDX.

Section I: Transaction Fees for Index Options

The Exchange's proposal to assess the same transaction fees for NDXP as it currently assesses for NDX is reasonable as NDXP will be an exclusively listed product on Nasdaq, Inc.-owned exchanges only.[13] Similar to NDX, the Exchange seeks to recoup the operational costs for listing proprietary products.[14] Also, pricing by symbol is a common practice on many U.S. options exchanges as a means to incentivize order flow to be sent to an exchange for execution in particular products. Other options exchanges price by symbol.[15] Further, the Exchange notes that with its products, market participants are offered an opportunity to either transact NDXP or separately execute PowerShares QQQ Trust (''QQQ'') options.[16] Offering products such as QQQ provides market participants with a variety of choices in selecting the product they desire to utilize to transact the Nasdaq 100® Index.[17] When exchanges are able to recoup costs associated with offering proprietary products, it incentivizes growth and competition for the innovation of additional products.

Furthermore, the Exchange believes that its proposal to assess a $0.75 per contract transaction fee for Non-Priority Customer orders in NDXP and no fee for Priority Customer orders, in each case identical to NDX, is reasonable because the fees are in line with its affiliate, Phlx. Phlx assesses a $0.75 per contract electronic options transaction charge for all non-customer orders in NDX and NDXP, and does not assess an electronic

[6] Non-Priority Customer includes Market Maker, Non-Nasdaq ISE Market Maker, Firm Proprietary/Broker-Dealer, and Professional Customer.

[7] A ''Crossing Order'' is an order executed in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, Price Improvement Mechanism (PIM) or submitted as a Qualified Contingent Cross order. For purposes of the Fee Schedule, orders executed in the Block Order Mechanism are also considered Crossing Orders.

[8] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Rule 100(a)(37A).

[9] The Exchange applies a route-out fee to executions of orders in all symbols that are routed to away markets in connection with the Plan. Specifically, Non-Priority Customer orders in Non-Select Symbols (*i.e.,* options overlying all symbols that are not in the Penny Program) pay a route-out fee of $0.95 per contract. NDX is a Non-Select Symbol. *See* Schedule of Fees, Section IV.F. *See also* Securities Exchange Act Release No. 80249 (March 15, 2017), 82 FR 14586 (March 21, 2017) (SR–ISE–2017–23) (establishing the $0.25 per contract Non-Priority Customer license surcharge for NDX, among other pricing changes); and Securities Exchange Act Release No. 81024 (June 26, 2017), 82 FR 29964 (June 30, 2017) (SR–ISE–2017–54) (applying the Non-Priority Customer license surcharge to orders in licensed products, including NDX, that are routed to away markets in connection with the Plan).

[10] NDXP is a Non-Select Symbol.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] NDXP is also currently listed on ISE's affiliated exchange, Nasdaq PHLX LLC (''Phlx'').

[14] For example, in analyzing an obvious error, the Exchange would have additional data points available in establishing a theoretical price for a multiply listed option as compared to a proprietary product, which requires additional analysis and administrative time to comply with Exchange rules to resolve an obvious error.

[15] *See* pricing for Russell 2000 Index (''RUT'') on Chicago Board Options Exchange, Incorporated's (''CBOE'') Fees Schedule and on CBOE C2 Exchange, Inc.'s (''C2'') Fees Schedule.

[16] QQQ is an exchange-traded fund based on the Nasdaq 100® Index.

[17] QQQ options overlie the same index as NDX, namely the Nasdaq 100® Index. This relationship between QQQ options and NDX options is similar to the relationship between RUT and the iShares Russell 2000 Index (''IWM''), which is the ETF on RUT.

options transaction charge for customer orders in NDX and NDXP.[18]

The Exchange believes that the proposed transaction fees for Non-Priority Customer orders in NDXP are equitable and not unfairly discriminatory because the Exchange will uniformly assess the $0.75 per contract fee to all such market participants. The Exchange also believes that it is equitable and not unfairly discriminatory to assess no transaction fees to Priority Customer orders in NDXP because Priority Customer orders bring valuable liquidity to the market, which in turn benefits other market participants.

Section II: Priority Customer Complex Rebates

The Exchange believes that its proposal to eliminate the Priority Customer Complex Rebates for NDXP, similar to NDX, is reasonable because even after the elimination of the rebate, Priority Customer complex orders in NDXP will not be assessed any complex order transaction fees. By contrast, public customer executions on C2 in RUT are subject to a $0.15 per contract transaction fee.[19]

The Exchange's proposal to eliminate the Priority Customer Complex Rebates for NDXP is equitable and not unfairly discriminatory because the Exchange will eliminate the rebate for all similarly situated members.

Section IV.C: Non-Priority Customer License Surcharge

The Exchange believes that its proposal to charge a $0.25 per contract Non-Priority Customer license surcharge for NDXP, similar to NDX, is reasonable because it is in line with the options surcharge of $0.25 per contract for non-customer transactions in NDX and NDXP on Phlx,[20] and is lower than the $0.45 per contract surcharge C2 applies to non-public customer transactions in RUT.[21] The Exchange also believes that its proposal to apply the Non-Priority Customer license surcharge to all executions in NDXP orders, including those orders that are routed to away markets in connection with the Plan, is reasonable because it will offset the costs associated with executing orders on away markets as well as the operational costs associated with listing proprietary products.

Further, the Exchange believes that its proposal to charge the Non-Priority Customer license surcharge for all executions in NDXP orders, including those orders that are executed on away markets in connection with the Plan is equitable and not unfairly discriminatory because the Exchange will apply the same surcharge for all similarly situated members in a similar manner. The Exchange also believes that it is equitable and not unfairly discriminatory to not assess the surcharge to Priority Customer orders in NDXP because Priority Customer orders bring valuable liquidity to the market, which in turn benefits other market participants.

Section IV.E: Marketing Fee

The Exchange believes that its proposal to exclude NDXP from the $0.70 per contract marketing fee is reasonable because the purpose of the marketing fee is to attract order flow to the Exchange. Because NDXP will be an exclusively listed product, a marketing fee whose purpose is to attract order flow to the Exchange is no longer necessary for NDXP.

The Exchange's proposal to exclude NDXP from the marketing fee is equitable and not unfairly discriminatory because the Exchange will apply this exclusion to all similarly situated members.

Section IV.H: Crossing Fee Cap

The Exchange believes that its proposal to exclude the Non-Priority Customer license surcharge and transaction fees for NDXP from the calculation of the monthly Crossing Fee Cap is reasonable because NDXP will be an exclusively listed product. Similar to NDX, which is also excluded from the Crossing Fee Cap, the Exchange seeks to recoup the operational costs for listing proprietary products.

The Exchange further believes that the proposed exclusion of NDXP from the Crossing Fee Cap is equitable and not unfairly discriminatory because the Exchange will apply the exclusion all similarly situated members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. All of the proposed changes are to adopt the current pricing applicable to NDX to NDXP, and the Exchange believes that the pricing for its proprietary products remains competitive with other options exchanges, as discussed above. In addition, the Exchange notes that with its products, market participants are offered an opportunity to either transact NDXP or separately execute QQQ options. Offering products such as QQQ provides market participants with a variety of choices in selecting the product they desire to utilize to transact the Nasdaq 100® Index.[22] Furthermore, the proposed pricing changes will apply uniformly to all similarly situated market participants, as discussed above. For the foregoing reasons, the Exchange does not believe that the proposed changes to apply the current pricing applicable to NDX to NDXP will impose an undue burden on competition.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[23] and Rule 19b–4(f)(2)[24] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[18] *See* Phlx's Pricing Schedule, Section II.

[19] *See* C2's Fees Schedule, Section 1.C.

[20] *See* Phlx's Pricing Schedule, Section II.

[21] *See* C2's Fees Schedule, Section 1.D.

[22] *See* note 17 above.

[23] 15 U.S.C. 78s(b)(3)(A)(ii).

[24] 17 CFR 240.19b–4(f)(2).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2018–38 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2018–38. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2018–38 and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83145; File No. SR–NYSE–2018–16]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make a Non-Substantive, Clarifying Change To Footnote 10 of Its Price List

May 1, 2018.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 19, 2018, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make a non-substantive, clarifying change to footnote 10 of its Price List. The Exchange proposes to implement these changes to its Price List effective April 20, 2018. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a non-substantive, clarifying change to footnote 10 of its Price List.

The Exchange proposes to implement this change to its Price List effective April 20, 2018.

Proposed Rule Change

Footnote 10 of the current Price List provides the following definition of ''last modified'' in connection with fees for Discretionary e-Quotes (''d-Quotes'') differentiated by time of entry (or last modification) above the first 750,000 average daily volume (''ADV'') of aggregate executions at the close based on the time of d-Quote entry:

> As used herein, ''last modified'' means the later of the order's entry time or the final modification or cancellation time for any d-Quote order with the same broker badge, entering firm mnemonic, symbol, and side.

The Exchange proposes a non-substantive change to clarify that the final modification or cancellation time in the second clause relates to d-Quotes designated for the closing auction.[4]

To effect this change, the Exchange would add the phrase ''designated for the close'' following ''d-Quote order.''

* * * * *

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(4) of the Act[6] in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers, and Section 6(b)(5) of the Act[7] in that it is designed to prevent fraudulent and manipulative

[25] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* NYSE Rule 70.25(a)(ii) (d-Quotes ''may include instructions to participate in the opening or closing transaction only'').

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] 15 U.S.C. 78f(b)(5).

acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed non-substantive change would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because they are designed to provide greater specificity and clarity to the Price List, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest. The proposed change to footnote 10 would not alter the application of any fees or rebates on the Price List. As such, the proposed changes would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national exchange system. In particular, the Exchange believes that the proposed change would provide greater clarity to members and member organizations and the public regarding the Exchange's Rules. It is in the public interest for rules to be accurate and concise so as to eliminate the potential for confusion.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[8] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the proposed changes will have no impact on competition as they are not designed to address any competitive issues but rather are designed to make non-substantive technical corrections and update the Exchange's Price List.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and subparagraph (f)(2) of Rule 19b–4[10] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[11] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2018–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2018–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2018–16 and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09575 Filed 5–4–18; 8:45 am]

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[8] 15 U.S.C. 78f(b)(8).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 15 U.S.C. 78s(b)(2)(B).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83142; File No. SR–NASDAQ–2018–032]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to List and Trade Exchange-Traded Managed Fund Shares of the Gabelli Pet Parent Fund Under Nasdaq Rule 5745

May 1, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 18, 2018, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade under Nasdaq Rule 5745 (Exchange-Traded Managed Fund Shares) the common shares (''Shares'') of the exchange-traded managed fund described herein (the ''Fund'').[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares of the Fund under Nasdaq Rule 5745, which governs the listing and trading of exchange-traded managed fund shares, as defined in Nasdaq Rule 5745(c)(1), on the Exchange.[4] The Fund listed below is registered with the Commission as an open-end investment company and has filed a registration statement on Form N–1A (''Registration Statement'') with the Commission. The Fund is a series of the Gabelli NextShares™ Trust (the ''Trust'') and will be advised by an investment adviser registered under the Investment Advisers Act of 1940 (''Adviser''), as described below. The Fund will be actively managed and will pursue the principal investment strategy noted below.[5]

Gabelli NextShares™ Trust

The Trust is registered with the Commission as an open-end investment company and has filed a Registration Statement with the Commission.[6] The following Fund is a series of the Trust.[7]

Gabelli Funds, LLC will be the Adviser to the Fund. The Adviser is not a registered broker-dealer, although it is affiliated with a broker-dealer. Gabelli Funds, LLC will also act as administrator to the Fund. The Adviser has implemented and will maintain a firewall with respect to its affiliated broker-dealer regarding access to information concerning the composition of and/or changes to the Fund's portfolio.[8] In addition, personnel who make decisions on the Fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the open-end fund's portfolio.

In the event that (a) the Adviser registers as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or a sub-adviser to the Fund is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a firewall with respect to its relevant personnel and/or such broker-dealer affiliate, if applicable, regarding access to information concerning the composition of and/or changes to the relevant Fund's portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio. G.distributors, LLC, will be the principal underwriter and distributor of the Fund's Shares. The Bank of New York Mellon will act as custodian and transfer agent. BNY Mellon Investment Servicing (US) Inc. will act as the sub-administrator to the Fund. Interactive Data Pricing and Reference Data, Inc. will be the IIV calculator to the Fund.

The Fund will be actively managed and will pursue the principal investment strategy described below.[9]

1. Gabelli Pet Parent Fund™—Companion Pets, Their Parents, and The Ecosystems (the ''Gabelli Pet Parent Fund'')

The Gabelli Pet Parent Fund seeks to provide capital appreciation. Under normal market conditions, the Gabelli Pet Parent Fund invests at least 80% of its net assets, plus borrowings for investment purposes, in common and preferred shares of publicly traded domestic and foreign companies of all capitalization ranges in the pet industry. The pet industry includes companies that offer services, support, and products for pets and pet parents including, without limitation, the following specific sectors: Food, healthcare, veterinary services, pharmaceuticals, wellness, nutrition, equipment, medical and dental supplies and services, recreation and entertainment, agriculture, infrastructure related to parks, toys and games, exercise, consumer products that support these sectors, and any other sector which supports the well-being of pets and pet parents.

Creations and Redemptions of Shares

Shares will be issued and redeemed on a daily basis for the Fund at the next-

[3] Except for the specific Fund information set forth below, this rule filing conforms to the rule filing, as modified by amendments 1 and 2 thereto, relating to the listing and trading on Nasdaq of the shares of 18 series of the Eaton Vance ETMF Trust and the Eaton Vance ETMF Trust II, as approved by the Commission in Securities Exchange Act Release No. 75499 (Jul. 21, 2015) (SR–NASDAQ–2015–036) and to the rule filing, as modified by amendment 1 thereto, relating to the listing and trading on Nasdaq of the shares of 5 series of the Gabelli NextShares Trust, as approved by the Commission in Securities Exchange Act Release No. 79377 (Nov. 22, 2016) (SR–NASDAQ–2016–134).

[4] The Commission approved Nasdaq Rule 5745 in Securities Exchange Act Release No. 34–73562 (Nov. 7, 2014), 79 FR 68309 (Nov. 14, 2014) (SR–NASDAQ–2014–020).

[5] Additional information regarding the Fund will be available on one of two free public websites (*www.gabelli.com* or *www.nextshares.com,* as indicated more fully below), as well as in the Registration Statement for the Fund.

[6] *See* Registration Statement on Form N–1A for the Trust dated April 4, 2018 (File Nos. 333–211881 and 811–23160). The descriptions of the Fund and the Shares contained herein conform to the Registration Statement.

[7] The Commission has issued an order granting the Trust and certain affiliates exemptive relief under the Investment Company Act. *See* Investment Company Act Release No. 31608 (May 19, 2015) (File No. 812–14438).

[8] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[9] *See* footnote 5.

determined net asset value (''NAV'')[10] in specified blocks of Shares called ''Creation Units.'' A Creation Unit will consist of at least 25,000 Shares. Creation Units may be purchased and redeemed by or through ''Authorized Participants.''[11] Purchases and sales of Shares in amounts less than a Creation Unit may be effected only in the secondary market, as described below, and not directly with the Fund.

The creation and redemption process for Funds [sic] may be effected ''in kind,'' in cash, or in a combination of securities and cash. Creation ''in kind'' means that an Authorized Participant—usually a brokerage house or large institutional investor— purchases the Creation Unit with a basket of securities equal in value to the aggregate NAV of the Shares in the Creation Unit. When an Authorized Participant redeems a Creation Unit in kind, it receives a basket of securities equal in value to the aggregate NAV of the Shares in the Creation Unit.[12]

Composition File

As defined in Nasdaq Rule 5745(c)(3), the Composition File is the specified portfolio of securities and/or cash that the Fund will accept as a deposit in issuing a Creation Unit of Shares, and the specified portfolio of securities and/or cash that the Fund will deliver in a redemption of a Creation Unit of Shares. The Composition File will be disseminated through the NSCC once each business day before the open of trading in Shares on such day and also will be made available to the public each day on a free website.[13] Because the Fund seeks to preserve the confidentiality of its current portfolio trading program, the Fund's Composition File generally will not be a pro rata reflection of the Fund's investment positions. Each security included in the Composition File will be a current holding of the Fund, but the Composition File generally will not include all of the securities in the Fund's portfolio or match the weightings of the included securities in the portfolio. Securities that the Adviser is in the process of acquiring for the Fund generally will not be represented in the Fund's Composition File until their purchase has been completed. Similarly, securities that are held in the Fund's portfolio but in the process of being sold may not be removed from its Composition File until the sale program is substantially completed. When creating and redeeming Shares in kind, the Fund will use cash amounts to supplement the in-kind transactions to the extent necessary to ensure that Creation Units are purchased and redeemed at NAV. The Composition File also may consist entirely of cash, in which case it will not include any of the securities in the Fund's portfolio.[14]

Transaction Fees

All persons purchasing or redeeming Creation Units of the Fund are expected to incur a transaction fee to cover the estimated cost to that Fund of processing the transaction, including the costs of clearance and settlement charged to it by NSCC or DTC, and the estimated trading costs (*i.e.,* brokerage commissions, bid-ask spread, and market impact) to be incurred in converting the Composition File to or from the desired portfolio holdings. The transaction fee is determined daily and will be limited to amounts determined by the Adviser to be appropriate to defray the expenses that the Fund incurs in connection with the purchase or redemption of Creation Units.

The purpose of transaction fees is to protect the Fund's existing shareholders from the dilutive costs associated with the purchase and redemption of Creation Units. Transaction fees will differ among funds and may vary over time for a given fund depending on the estimated trading costs for its portfolio positions and Composition File, processing costs and other considerations. Funds that specify greater amounts of cash in their Composition File may impose higher transaction fees.

In addition, funds that include in their Composition File instruments that clear through DTC may impose higher transaction fees than funds with a Composition File consisting solely of instruments that clear through NSCC, because DTC may charge more than NSCC in connection with Creation Unit transactions.[15] The transaction fees applicable to the Fund's purchases and redemptions on a given business day will be disseminated through the NSCC prior to the open of market trading on that day and also will be made available to the public each day on a free website.[16] In all cases, the transaction fees will be limited in accordance with the requirements of the Commission applicable to open-end management investment companies offering redeemable securities.

NAV-Based Trading

Because Shares will be listed and traded on the Exchange, Shares will be available for purchase and sale on an intraday basis. Shares will be purchased and sold in the secondary market at prices directly linked to the Fund's next-determined NAV using a new trading protocol called ''NAV-Based Trading.''[17] All bids, offers, and execution prices of Shares will be expressed as a premium/discount (which may be zero) to the Fund's next-determined NAV (*e.g.,* NAV-$0.01, NAV+$0.01). The Fund's NAV will be determined each business day, normally

[10] As with other registered open-end investment companies, NAV generally will be calculated daily Monday through Friday as of the close of regular trading on the New York Stock Exchange, normally 4:00 p.m. Eastern Time (''E.T.''). NAV will be calculated by dividing the Fund's net asset value by the number of Shares outstanding. Information regarding the valuation of investments in calculating the Fund's NAV will be contained in the Registration Statement for its Shares.

[11] ''Authorized Participants'' will be either: (1) ''participating parties,'' *i.e.,* brokers or other participants in the Continuous Net Settlement System (''CNS System'') of the National Securities Clearing Corporation (''NSCC''), a clearing agency registered with the Commission and affiliated with the Depository Trust Company (''DTC''), or (2) DTC participants, which in either case have executed participant agreements with the Fund's distributor and transfer agent regarding the creation and redemption of Creation Units. Investors will not have to be Authorized Participants in order to transact in Creation Units, but must place an order through and make appropriate arrangements with an Authorized Participant for such transactions.

[12] In compliance with Nasdaq Rule 5745(b)(5), which applies to Shares based on an international or global portfolio, the Trust's application for exemptive relief under the Investment Company Act states that the Fund will comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933, as amended (15 U.S.C. 77a).

[13] The free website containing the Composition File will be *www.nextshares.com.*

[14] In determining whether the Fund will issue or redeem Creation Units entirely on a cash basis, the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, the Adviser may be able to obtain better execution for the Fund than Authorized Participants because of the Adviser's size, experience and potentially stronger relationships in the fixed-income markets.

[15] Authorized Participants that participate in the CNS System of the NSCC are expected to be able to use the enhanced NSCC/CNS process for effecting in-kind purchases and redemptions of ETFs (the ''NSCC Process'') to purchase and redeem Creation Units of the Fund that limit the composition of their baskets to include only NSCC Process-eligible instruments (generally domestic equity securities and cash). Because the NSCC Process is generally more efficient than the DTC clearing process, NSCC is likely to charge the Fund less than DTC to settle purchases and redemptions of Creation Units.

[16] The free website will be *www.nextshares.com.*

[17] Aspects of NAV-Based Trading are protected intellectual property subject to issued and pending U.S. patents held by NextShares Solutions LLC (''NextShares Solutions''), a wholly owned subsidiary of Eaton Vance Corp. Nasdaq has entered into a license agreement with NextShares Solutions to allow for NAV-Based Trading on the Exchange of exchange-traded managed funds that have themselves entered into license agreements with NextShares Solutions.

as of 4:00 p.m., E.T. Trade executions will be binding at the time orders are matched on Nasdaq's facilities, with the transaction prices contingent upon the determination of NAV.

Trading Premiums and Discounts

Bid and offer prices for Shares will be quoted throughout the day relative to NAV. The premium or discount to NAV at which Share prices are quoted and transactions are executed will vary depending on market factors, including the balance of supply and demand for Shares among investors, transaction fees, and other costs in connection with creating and redeeming Creation Units of Shares, the cost and availability of borrowing Shares, competition among market makers, the Share inventory positions and inventory strategies of market makers, the profitability requirements and business objectives of market makers, and the volume of Share trading. Reflecting such market factors, prices for Shares in the secondary market may be above, at or below NAV. Funds with higher transaction fees may trade at wider premiums or discounts to NAV than other funds with lower transaction fees, reflecting the added costs to market makers of managing their Share inventory positions through purchases and redemptions of Creation Units.

Because making markets in Shares will be simple to manage and low risk, competition among market makers seeking to earn reliable, low-risk profits should enable the Shares to routinely trade at tight bid-ask spreads and narrow premiums/discounts to NAV. As noted below, the Fund will maintain a public website that will be updated on a daily basis to show current and historical trading spreads and premiums/discounts of Shares trading in the secondary market.[18]

Transmitting and Processing Orders

Member firms will utilize certain existing order types and interfaces to transmit Share bids and offers to Nasdaq, which will process Share trades like trades in shares of other listed securities.[19] In the systems used to transmit and process transactions in Shares, the Fund's next-determined NAV will be represented by a proxy price (*e.g.,* 100.00) and a premium/discount of a stated amount to the next-determined NAV to be represented by the same increment/decrement from the proxy price used to denote NAV (*e.g.,* NAV–$0.01 would be represented as 99.99; NAV+$0.01 as 100.01).

To avoid potential investor confusion, Nasdaq will work with member firms and providers of market data services to seek to ensure that representations of intraday bids, offers, and execution prices of Shares that are made available to the investing public follow the ''NAV–$0.01/NAV+$0.01'' (or similar) display format. All Shares listed on the Exchange will have a unique identifier associated with their ticker symbols, which would indicate that the Shares are traded using NAV-Based Trading. Nasdaq makes available to member firms and market data services certain proprietary data feeds that are designed to supplement the market information disseminated through the consolidated tape (''Consolidated Tape'').

Specifically, the Exchange will use the Nasdaq Basic and Nasdaq Last Sale data feeds to disseminate intraday price and quote data for Shares in real time in the ''NAV–$0.01/NAV+$0.01'' (or similar) display format. Member firms could use the Nasdaq Basic and Nasdaq Last Sale data feeds to source intraday Share prices for presentation to the investing public in the ''NAV–$0.01/NAV+$0.01'' (or similar) display format.

Alternatively, member firms could source intraday Share prices in proxy price format from the Consolidated Tape and other Nasdaq data feeds (*e.g.,* Nasdaq TotalView and Nasdaq Level 2) and use a simple algorithm to convert prices into the ''NAV–$0.01/NAV+$0.01'' (or similar) display format. As noted below, prior to the commencement of trading in the Fund, the Exchange will inform its members in an Information Circular of the identities of the specific Nasdaq data feeds from which intraday Share prices in proxy price format may be obtained.

Intraday Reporting of Quotes and Trades

All bids and offers for Shares and all Share trade executions will be reported intraday in real time by the Exchange to the Consolidated Tape[20] and separately disseminated to member firms and market data services through the Exchange data feeds listed above. The Exchange will also provide the member firms participating in each Share trade with a contemporaneous notice of trade execution, indicating the number of Shares bought or sold and the executed premium/discount to NAV.[21]

Final Trade Pricing, Reporting, and Settlement

All executed Share trades will be recorded and stored intraday by Nasdaq to await the calculation of the Fund's end-of- day NAV and the determination of final trade pricing. After the Fund's NAV is calculated and provided to the Exchange, Nasdaq will price each Share trade entered into during the day at the Fund's NAV plus/minus the trade's executed premium/discount. Using the final trade price, each executed Share trade will then be disseminated to member firms and market data services via an FTP file to be created for exchange-traded managed funds and confirmed to the member firms participating in the trade to supplement the previously provided information to include final pricing.[22] After the pricing is finalized, Nasdaq will deliver the Share trading data to NSCC for clearance and settlement, following the same processes used for the clearance and settlement of trades in other exchange-traded securities.

Availability of Information

Prior to the commencement of market trading in Shares, the Fund will be required to establish and maintain a public website through which its current prospectus may be downloaded.[23] In addition, a separate website (*www.nextshares.com*) will include additional information concerning the Fund updated on a daily basis, including the prior business day's NAV, and the following trading information for such business day expressed as premiums/discounts to NAV: (a) Intraday high, low, average, and closing prices of Shares in Exchange trading; (b) the midpoint of the highest bid and lowest offer prices as of the close of Exchange trading, expressed as a premium/discount to NAV (the ''Closing Bid/Ask Midpoint''); and (c) the spread between highest bid and lowest offer prices as of the close of Exchange trading (the ''Closing Bid/Ask

[18] The website containing this information will be *www.gabelli.com.*

[19] As noted below, all orders to buy or sell Shares that are not executed on the day the order is submitted will be automatically cancelled as of the close of trading on such day. Prior to the commencement of trading in the Fund, the Exchange will inform its members in an Information Circular of the effect of this characteristic on existing order types.

[20] Due to systems limitations, the Consolidated Tape will report intraday execution prices and quotes for Shares using a proxy price format. As noted, Nasdaq will separately report real-time execution prices and quotes to member firms and providers of market data services in the ''NAV–$0.01/NAV+$0.01'' (or similar) display format, and otherwise seek to ensure that representations of intraday bids, offers and execution prices for Shares that are made available to the investing public follow the same display format.

[21] All orders to buy or sell Shares that are not executed on the day the order is submitted will be automatically cancelled as of the close of trading on such day.

[22] File Transfer Protocol (''FTP'') is a standard network protocol used to transfer computer files on the internet. Nasdaq will arrange for the daily dissemination of an FTP file with executed Share trades to member firms and market data services.

[23] *See* footnote 18.

Spread.''). The *www.nextshares.com* website will also contain charts showing the frequency distribution and range of values of trading prices, Closing Bid/Ask Midpoints, and Closing Bid/Ask Spreads over time.

The Composition File will be disseminated through the NSCC before the open of trading in Shares on each business day and also will be made available to the public each day on a free website as noted above.[24] Consistent with the disclosure requirements that apply to traditional open-end investment companies, a complete list of current Fund portfolio positions will be made available at least once each calendar quarter, with a reporting lag of not more than 60 days. The Fund may provide more frequent disclosures of portfolio positions at their discretion.

Reports of Share transactions will be disseminated to the market and delivered to the member firms participating in the trade contemporaneous with execution. Once the Fund's daily NAV has been calculated and disseminated, Nasdaq will price each Share trade entered into during the day at the Fund's NAV plus/minus the trade's executed premium/discount. Using the final trade price, each executed Share trade will then be disseminated to member firms and market data services via an FTP file to be created for exchange-traded managed funds and confirmed to the member firms participating in the trade to supplement the previously provided information to include final pricing.

Information regarding NAV-based trading prices, best bids and offers for Shares, and volume of Shares traded will be continuously available on a real-time basis throughout each trading day on brokers' computer screens and other electronic services.

Initial and Continued Listing

Shares will conform to the initial and continued listing criteria as set forth under Nasdaq Rule 5745. A minimum of 50,000 Shares and no less than two Creation Units of the Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily (on each business day that the New York Stock Exchange is open for trading) and provided to Nasdaq via the Mutual Fund Quotation Service (''MFQS'') by the fund accounting agent. As soon as the NAV is entered into MFQS, Nasdaq will disseminate the NAV to market participants and market data vendors via the Mutual Fund Dissemination Service (''MFDS'') so all firms will receive the NAV per share at the same time. The Reporting Authority [25] also will implement and maintain, or ensure that the Composition File will be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the Fund's portfolio positions and changes in the positions.

For the Fund, an estimated value of an individual Share, defined in Nasdaq Rule 5745(c)(2) as the ''Intraday Indicative Value,'' will be calculated and disseminated at intervals of not more than 15 minutes throughout the Regular Market Session [26] when Shares trade on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the IIV will be calculated on an intraday basis and provided to Nasdaq for dissemination via the Nasdaq Global Index Service (''GIDS'').

The IIV will be based on current information regarding the value of the securities and other assets held by the Fund.[27] The purpose of the IIVs is to enable investors to estimate the next-determined NAV so they can determine the number of Shares to buy or sell if they want to transact in an approximate dollar amount (*e.g.,* if an investor wants to acquire approximately $5,000 of the Fund, how many Shares should the investor buy?).[28]

The Adviser is not a registered broker-dealer, although it is affiliated with a broker-dealer. The Adviser has implemented and will maintain a firewall with respect to its broker-dealer affiliate regarding access to information concerning the composition of and/or changes to the Fund's portfolio. In addition, personnel who make decisions on the Fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the open-end fund's portfolio.

In the event that (a) the Adviser registers as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or a sub-adviser to the Fund is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and will maintain a firewall with respect to its relevant personnel and/or such broker-dealer affiliate, if applicable, regarding access to information concerning the composition of and/or changes to the Fund's portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

Trading Halts

The Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in Shares. Nasdaq will halt trading in Shares under the conditions specified in Nasdaq Rule 4120 and in Nasdaq Rule 5745(d)(2)(C). Additionally, Nasdaq may cease trading Shares if other unusual conditions or circumstances exist which, in the opinion of Nasdaq, make further dealings on Nasdaq detrimental to the maintenance of a fair and orderly market. To manage the risk of a non-regulatory Share trading halt, Nasdaq has in place back-up processes and procedures to ensure orderly trading. Because, in NAV-Based Trading, all trade execution prices are linked to end-of-day NAV, buyers and sellers of Shares should be less exposed to risk of loss due to intraday trading halts than buyers and sellers of conventional exchange-traded funds (''ETFs'') and other exchange-traded securities.

Trading Rules

Nasdaq deems Shares to be equity securities, thus rendering trading in Shares to be subject to Nasdaq's existing rules governing the trading of equity securities. Nasdaq will allow trading in Shares from 9:30 a.m. until 4:00 p.m. E.T.

Every order to trade Shares of the Fund is subject to the proxy price protection threshold of plus/minus $1.00, which determines the lower and upper threshold for the life of the order and whereby the order will be cancelled at any point if it exceeds $101.00 or falls below $99.00, the established thresholds.[29] With certain exceptions,

[24] *See* footnote 13.

[25] *See* Nasdaq Rule 5745(c)(4).

[26] *See* Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4 a.m. to 9:30 a.m. E.T.; (2) Regular Market Session from 9:30 a.m. to 4 p.m. or 4:15 p.m. E.T.; and (3) Post-Market Session from 4 p.m. or 4:15 p.m. to 8 p.m. E.T.).

[27] IIVs disseminated throughout each trading day would be based on the same portfolio as used to calculate that day's NAV. The Fund will reflect purchases and sales of portfolio positions in its NAV the next business day after trades are executed.

[28] Because, in NAV-Based Trading, prices of executed trades are not determined until the reference NAV is calculated, buyers and sellers of Shares during the trading day will not know the final value of their purchases and sales until the end of the trading day. The Fund's Registration Statement, website and any advertising or marketing materials will include prominent disclosure of this fact. Although IIVs may provide useful estimates of the value of intraday trades, they cannot be used to calculate with precision the dollar value of the Shares to be bought or sold.

[29] *See* Nasdaq Rule 5745(h).

each order also must contain the applicable order attributes, including routing instructions and time-in-force information, as described in Nasdaq Rule 4703.[30]

Surveillance

The Exchange represents that trading in Shares will be subject to the existing trading surveillances, administered by both Nasdaq and the Financial Industry Regulatory Authority, Inc. (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[31] The Exchange represents that these procedures are adequate to properly monitor trading of Shares on the Exchange and to deter and detect violations of Exchange rules and applicable federal securities laws.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

FINRA, on behalf of the Exchange, will communicate as needed with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG'') [32] regarding trading in Shares, and in exchange-traded securities and instruments held by the Fund (to the extent such exchange-traded securities and instruments are known through the publication of the Composition File and periodic public disclosures of the Fund's portfolio holdings), and FINRA may obtain trading information regarding such trading from other markets and other entities.

In addition, the Exchange may obtain information regarding trading in Shares, and in exchange-traded securities and instruments held by the Fund (to the extent such exchange-traded securities and instruments are known through the publication of the Composition File and periodic public disclosures of the Fund's portfolio holdings), from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement.

In addition, the Exchange also has a general policy prohibiting the distribution of material non-public information by its employees.

Information Circular

Prior to the commencement of trading in the Fund, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and noting that Shares are not individually redeemable); (2) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in Shares to customers; (3) how information regarding the IIV and Composition File is disseminated; (4) the requirement that members deliver a prospectus to investors purchasing Shares prior to or concurrently with the confirmation of a transaction; and (5) information regarding NAV-Based Trading protocols.

As noted above, all orders to buy or sell Shares that are not executed on the day the order is submitted will be automatically cancelled as of the close of trading on such day. The Information Circular will discuss the effect of this characteristic on existing order types. The Information Circular also will identify the specific Nasdaq data feeds from which intraday Share prices in proxy price format may be obtained.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a summary prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

The Information Circular also will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares and the applicable NAV calculation time for the Shares. The Information Circular will disclose that information about the Shares will be publicly available at *www.nextshares.com.*

Information regarding the Fund's trading protocols will be disseminated to Nasdaq members in accordance with current processes for newly listed products. Nasdaq intends to provide its members with a detailed explanation of NAV-Based Trading through a Trading Alert issued prior to the commencement of trading in Shares on the Exchange.

Continued Listing Representations

All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, (c) dissemination and availability of the reference asset or intraday indicative values, or (d) the applicability of Exchange listing rules shall constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act,[33] in general, and Section 6(b)(5) of the Act,[34] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares would be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Nasdaq Rule 5745. The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of Shares on Nasdaq and to deter and detect violations of Exchange rules and the applicable federal securities laws. The Adviser is not registered as a broker-dealer, but it is affiliated with a broker-dealer. The Adviser has implemented

[30] *See* Nasdaq Rule 5745(b)(6).

[31] FINRA provides surveillance of trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[32] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Fund's portfolio may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[33] 15 U.S.C. 78f(b).

[34] 15 U.S.C. 78f(b)(5).

and will maintain a ''firewall'' between the Adviser and its broker-dealer affiliate with respect to access to information concerning the composition of and/or changes to the Fund's portfolio holdings. The Exchange may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement, to the extent necessary.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest. The Exchange will obtain a representation from the issuer of Shares that the NAV per Share will be calculated on each business day that the New York Stock Exchange is open for trading and that the NAV will be made available to all market participants at the same time. In addition, a large amount of information would be publicly available regarding the Fund and the Shares, thereby promoting market transparency.

Prior to the commencement of market trading in Shares, the Fund will be required to establish and maintain a public website through which its current prospectus may be downloaded.[35] In addition, a separate website (*www.nextshares.com*) will display additional information concerning the Fund updated on a daily basis, including the prior business day's NAV, and the following trading information for such business day expressed as premiums/discounts to NAV: (a) Intraday high, low, average and closing prices of Shares in Exchange trading; (b) the Closing Bid/Ask Midpoint; and (c) the Closing Bid/Ask Spread.

The *www.nextshares.com* website will also contain charts showing the frequency distribution and range of values of trading prices, Closing Bid/Ask Midpoints, and Closing Bid/Ask Spreads over time. The Composition File will be disseminated through the NSCC before the open of trading in Shares on each business day and also will be made available to the public each day on a free website, as noted above.[36] The Exchange will obtain a representation from the issuer of the Shares that the IIV will be calculated and disseminated on an intraday basis at intervals of not more than 15 minutes during trading on the Exchange and provided to Nasdaq for dissemination via GIDS. A complete list of current portfolio positions for the Fund will be made available at least once each calendar quarter, with a reporting lag of not more than 60 days. The Fund may provide more frequent disclosures of portfolio positions at its discretion.

Transactions in Shares will be reported to the Consolidated Tape at the time of execution in proxy price format and will be disseminated to member firms and market data services through Nasdaq's trading service and market data interfaces, as defined above. Once the Fund's daily NAV has been calculated and the final price of its intraday Share trades has been determined, Nasdaq will deliver a confirmation with final pricing to the transacting parties. At the end of the day, Nasdaq will also post a newly created FTP file with the final transaction data for the trading and market data services.

The Exchange expects that information regarding NAV-based trading prices and volumes of Shares traded will be continuously available on a real-time basis throughout each trading day on brokers' computer screens and other electronic services. Because Shares will trade at prices based on the next-determined NAV, investors will be able to buy and sell individual Shares at a known premium or discount to NAV that they can limit by using limit orders at the time of order entry. Trading in Shares will be subject to Nasdaq Rules 5745(d)(2)(B) and (C), which provide for the suspension of trading or trading halts under certain circumstances, including if, in the view of the Exchange, trading in Shares becomes inadvisable.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of the Fund, which seeks to provide investors with access to a broad range of actively managed investment strategies in a structure that offers the cost and tax efficiencies and shareholder protections of ETFs, while removing the requirement for daily portfolio holdings disclosure to ensure a tight relationship between market trading prices and NAV.

For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the introduction of the Fund will promote competition by making available to investors an actively managed investment strategy in a structure that offers the cost and tax efficiencies and shareholder protections of ETFs, while removing the requirement for daily portfolio holdings disclosure to ensure a tight relationship between market trading prices and NAV. Moreover, the Exchange believes that the proposed method of Share trading would provide investors with transparency of trading costs, and the ability to control trading costs using limit orders, that is not available for conventionally traded ETFs.

These developments could significantly enhance competition to the benefit of the markets and investors.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[37] and Rule 19b–4(f)(6) thereunder.[38]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[39] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[40] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Commission notes that it has approved a number of filings by the Exchange to list and trade NextShares filings under Exchange Rule

[35] *See* footnote 18.

[36] *See* footnote 13.

[37] 15 U.S.C. 78s(b)(3)(A).

[38] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[39] 17 CFR 240.19b–4(f)(6).

[40] 17 CFR 240.19b–4(f)(6)(iii).

5745.[41] This proposed rule change is consistent with those filings and raises no novel issues. The Shares will be purchased and sold in the secondary market at prices directly linked to the Fund's next-determined NAV using the trading protocol called ''NAV-Based Trading,'' and the Fund's permitted investments will be consistent with those approved in prior filings. Accordingly, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the operative delay and designates the proposed rule change operative upon filing.[42]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2018–032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2018–032. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2018–032, and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09572 Filed 5–4–18; 8:45 am]

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[41] *See, e.g.,* Securities Exchange Act Release Nos. 82730 (Feb. 16, 2018), 83 FR 8118 (Feb. 23, 2018) (SR–NASDAQ–2017–131) (Order Granting Approval of a Proposed Rule Change To List and Trade the Shares of the Reinhart Intermediate Bond NextShares Fund Under Nasdaq Rule 5745) and 82564 (Jan. 22, 2018), 83 FR 3842 (Jan. 26, 2018) (SR–NASDAQ–2017–123) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Causeway International Value NextShares™ and the Causeway Global Value NextShares™ Under Nasdaq Rule 5745).

[42] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83147; File No. SR–IEX–2018–09]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify its Fee Schedule To Charge a More Deterministic Fee of $0.0003 Per Share for Executions at or Above $1.00 That Result From Removing Liquidity With an Order That is Executable at the Far Side of the NBBO

May 1, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 20, 2018, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 (''Act''),[4] and Rule 19b–4 thereunder,[5] Investors Exchange LLC (''IEX'' or ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to modify its Fee Schedule, pursuant to IEX Rule 15.110(a) and (c), to charge a more deterministic fee of $0.0003 per share for executions at or above $1.00 that result from removing liquidity with an order that is executable at the far side of the NBBO [6] (the ''Spread-Crossing Remove Fee''). Consistent with the Exchange's existing Fee Schedule, executions below $1.00 will be 0.30% of the total dollar value of the transaction. Changes to the Fee Schedule pursuant to this proposal are effective upon filing and will be operative on May 1, 2018.

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] As defined by Regulation NMS Rule 600(b)(42). 17 CFR 242.600.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its Fee Schedule, pursuant to IEX Rule 15.110(a) and (c), to charge a more deterministic fee of $0.0003 per share for executions at or above $1.00 that result from removing liquidity with an order that is executable at the far side of the NBBO (*i.e.,* a buy order that is executable at the NBO or higher, or a sell order that is executable at the NBB or lower). In an effort to incentivize Members to submit displayed orders to the Exchange, the Exchange currently charges a fee of $0.0003 per share (or 0.30% of the total dollar value of the transaction for securities priced below $1.00) to Members for executions on IEX that provide or take resting interest with displayed priority (*i.e.,* an order or portion of a reserve order that is booked and ranked with display priority on the Order Book).[7] Furthermore, the Exchange currently charges $0.0009 per share (or 0.30% of the total dollar value of the transaction for securities priced below $1.00) to Members for executions on IEX that provide or take resting interest with non-displayed priority (*i.e.,* an order or portion of a reserve order that is booked and ranked with non-displayed priority on the Order Book).[8] The Exchange does not charge any fee to Members for executions on IEX when the adding and removing order originated from the same Exchange Member.[9]

After informal discussions with various Members, the Exchange recognizes that some Members may be dissuaded from seeking to access IEX quotations at the NBBO due to the variability in execution fees when routing orders to the Exchange that are executable at the far side of the NBBO and intended to trade against the Exchange's displayed quotation, but inadvertently remove non-displayed liquidity resting at or within the spread. While such spread-crossing orders would receive price improvement equal to the delta between the execution price and the far side quotation (*i.e.,* the difference between the trade price and the NBO (NBB) for buy (sell) orders),[10] the potential for interacting with non-displayed liquidity resting within the spread, and therefore being assessed the Non-Displayed Match Fee of $0.0009 versus the Displayed Match Fee of $0.0003, makes it difficult for Members to estimate access fees on a pre-trade basis, which the Exchange believes thereby presents difficulties for some Members when determining which venues to route marketable orders to.[11]

In order to reduce the variability in fees to access liquidity on the Exchange and thereby incentivize Members to route more orders to the Exchange that are executable at the far side of the NBBO, the Exchange is proposing to offer a more deterministic Spread-Crossing Remove Fee of $0.0003 per share to all executions at or above $1.00 that result from removing liquidity with a buy (sell) order that is executable at the NBO (NBB). Consistent with the Exchange's existing Fee Schedule, executions below $1.00 will be 0.30% of the total dollar value of the transaction. Members will receive a Fee Code of ''N'' on execution reports provided by the Exchange for transactions that receive the Spread-Crossing Remove Fee.[12]

The Exchange believes that incentivizing additional spread-crossing interest by offering the proposed Spread-Crossing Remove Fee will enhance public price discovery and overall execution quality on the Exchange in several ways. First, as described above, to the extent spread-crossing interest removes non-displayed liquidity within the spread, the spread-crossing orders will receive price improvement equal to the delta between the execution price and the far side quotation, while the non-displayed resting interest will have received the benefit of trading passively and also capturing the spread in part. Similarly, to the extent spread-crossing interest removes displayed liquidity resting at the NBBO, such resting displayed liquidity will have increased opportunities to capture the full spread. If market makers and other Members are more frequently capturing the spread when resting displayed orders on the Exchange, such Members may be incentivized to enter additional aggressively priced displayed orders on the Exchange, thereby contributing to public price discovery, consistent with the overall goal of enhancing market quality.

Pursuant to Rules 11.190(a)(1)–(3), the Exchange offers three general order types—market orders, limit orders, and pegged orders—each of which have distinct functional behaviors, and are further controlled by various User-defined order parameters that dictate additional functional behaviors of the order within the Exchange's System.[13] Orders entered on the Exchange are eligible to remove liquidity on entry pursuant to the distinct behavior of the User-selected order type and order parameters. In addition, non-displayed orders that are resting on the Order Book and eligible to trade at least as aggressively as the Midpoint Price are eligible to remove liquidity on Order Execution Recheck, or ''Book Recheck'', pursuant to Rule 11.230(a)(4)(d). Book Recheck is a process within the IEX System that detects new trading opportunities for resting orders upon a change to the Order Book, the NBBO, or as part of processing inbound messages, resulting in an invitation for non-displayed orders to attempt to remove liquidity from the contra side.[14]

Pursuant to the Exchange's Rules, in addition to the terms of each order type and order parameter, every order is subject to various legal and technical constraints that are designed to optimize order interactions within the System, and to comply with the Act and the rules and regulations thereunder. Rule

[7] This pricing is referred to by the Exchange as ''Displayed Match Fee'' with a Fee Code of 'L' provided by the Exchange on execution reports. *See* the Investors Exchange Fee Schedule, available on the Exchange public website.

[8] This pricing is referred to by the Exchange as ''Non-Displayed Match Fee'' with a Fee Code of 'I' provided by the Exchange on execution reports. *See* the Investors Exchange Fee Schedule, available on the Exchange public website.

[9] This pricing is referred to by the Exchange as ''Internalization Fee'' with a Fee Code of 'S' provided by the Exchange on execution reports. Orders from different market participant identifiers of the same broker dealer, with the same Central Registration Depository registration number, are treated as originating from the same Exchange Member. *See* the Investors Exchange Fee Schedule, available on the Exchange public website.

[10] The Exchange notes that when handling client orders as agent, IEX Members must ensure they are satisfying their duty of best execution, which requires that in any transaction for or with a customer or a customer of another broker-dealer, a member and persons associated with a member shall use reasonable diligence to ascertain the best market for the subject security and buy or sell in such market so that the resultant price to the customer is as favorable as possible under prevailing market conditions. Members must also conduct regular and rigorous reviews of execution quality in order to determine which market center to route customer orders, and should explicitly consider the extent to which an order may obtain price improvement at other venues. *See* FINRA Rule 5310, including Supplementary Material .09 thereto.

[11] The Exchange notes that FINRA has released guidance clarifying that firms should not allow access fees charged by venues to inappropriately affect their routing decisions, and, in general, a firm's routing decisions should not be unduly influenced by a particular venue's fee or rebate structure. *See* FINRA Regulatory Notice 15–46 (November 2015) at 6.

[12] Pursuant to the Exchange's existing Fee Schedule, a Fee Code of ''N'' applies to executions that are part of an IPO Auction. Accordingly, the Exchange is proposing to replace the Fee Code for executions in an IPO Auction with a Fee Code of ''P''.

[13] *See* Rule 11.190(b) (Order Parameters) for a full description of the available order parameters.

[14] *See* Rule 11.230(a)(4)(d), which provides a complete description of Book Recheck.

11.190(f)(1)(Order Collars) describes the IEX Order Collar, which prevents any incoming order or order resting on the Order Book, including those marked ISO, from executing at a price outside of the Order Collar price range (*i.e.,* prevents buy orders from trading at prices above the collar and prevents sell orders from trading at prices below the collar).[15] Furthermore, Rule 11.190(h)(Price Sliding) describes the Exchange's price sliding processes that are designed to ensure compliance with Regulation NMS (including the Plan to Address Extraordinary Market Volatility pursuant to Rule 608 thereunder (the ''LULD Plan''),[16] as well as Rule 201 of Regulation SHO.[17]

If an order—based on market conditions, User instructions, applicable IEX Rules and/or the Act and the rules and regulations thereunder—is not executable at the far side of the NBBO, such order will not be eligible for the Spread-Crossing Remove Fee. Specifically, for a buy (sell) order to be deemed ''executable'' at the NBO (NBB), in the case of a market order, the applicable IEX Order Collar and the price of the Upper (Lower) LULD Price Band, as well as the result of any other price sliding necessary pursuant to Rule 11.190(h), must be marketable to the NBO (NBB) upon entry, because market orders, despite not having a maximum (minimum) price at which the User is willing to buy (sell), remain constrained by the least aggressive of the IEX Order Collar and the LULD Price Band, as well as the result of any other price sliding necessary pursuant to Rule 11.190(h). For example, in a Tier 1 security, if the NBBO is $10.10 by $10.20, the IEX Order Collar is $9.13 by $11.16, and the LULD Price Band is $9.64 by $10.65, a market order to buy (sell) that removes liquidity from the Order Book (against either displayed or non-displayed liquidity on the Order Book) will receive the Spread-Crossing Remove Fee, because the Upper (Lower) LULD Price Band of $10.65 ($9.64) (which is less aggressive than the IEX Order Collar, and therefore controlling), is marketable to the NBO (NBB) of $10.20 ($10.10).

In the case of a limit order, the User-defined and System-adjusted limit price (*i.e.,* the price at which the order is eligible to execute after accounting for the User-defined limit price, the IEX Order Collar, and the LULD Price Band, as well as the result of any other price sliding necessary pursuant to Rule 11.190(h)) must be executable at the NBO (NBB) upon entry, or on Book Recheck. For example, in a Tier 1 security, if the NBBO is $10.10 by $10.20, the IEX Order Collar is $9.13 by $11.16, and the LULD Price Band is $9.64 by $10.65, a limit order to buy with a limit price of $10.20 that removes liquidity from the Order Book (against either displayed or non-displayed liquidity on the Order Book) will receive the Spread-Crossing Remove Fee, because the User-defined limit price is marketable to the NBO, and less aggressive than the IEX Order Collar and the LULD Price Band, and does not otherwise necessitate additional price sliding pursuant to Rule 11.190(h)(4).

As a general matter, pegged orders do not qualify for the Spread-Crossing Remove Fee, because such orders, by their terms, are explicitly designed to capture the spread in full or in part by executing at prices that are equal to or more passive than the Midpoint Price. However, pursuant to Rule 11.190(h)(3)(C)(i), in the event the market becomes locked (*i.e.,* the price of the NBB is equal to the price of NBO), the Exchange considers the Midpoint Price to be equal to the locking price. Therefore, in a locked market, Midpoint Peg[18] and Discretionary Peg[19] orders that remove liquidity at the locking price on entry or on Book Recheck will receive the Spread-Crossing Remove Fee. For example, if the NBBO is locked at $10.10 by $10.10, a Midpoint Peg order to buy (sell) that removes liquidity at $10.10 will receive the Spread-Crossing Remove Fee. In contrast, Primary Peg orders are never eligible to remove liquidity, and therefore will never receive the Spread-Crossing Remove Fee.[20]

Similarly, when a short sale price test restriction[21] is in effect, short sale orders not marked short exempt that are priced at or more aggressive than the NBB are subject to the short sale price sliding process pursuant to Rule 11.190(h)(4) and are therefore never executable at or below the NBB. Accordingly, when a short sale price test restriction is in effect, short sale orders not marked short exempt that are priced to execute at or below the NBB will not receive the Spread-Crossing Remove Fee. For example, for a security subject to the short sale price test restriction, if the NBBO is $10.10 by $10.20, and IEX receives a non-displayed short sale limit order not marked short exempt with a limit price of $10.10, such order is ineligible for execution at its limit price pursuant to Rule 11.190(h)(4)(B), would only be executable above the current NBB upon entry or on Book Recheck, and would otherwise be repriced and ranked by the System on the Order Book non-displayed pursuant to the Midpoint Price Constraint at the current Midpoint Price.[22] Accordingly, such order is never executable at the NBB, and therefore would not receive the Spread-Crossing Remove Fee.

Finally, in the case of a crossed market (*i.e.,* when the price of the NBB is higher than the NBO), all removers of liquidity will receive the Spread-Crossing Remove Fee. For example, if the NBBO is crossed at $10.13 by

[15] The Order Collar price range is calculated by applying the numerical guidelines for clearly erroneous executions to the ''Order Collar Reference Price'', which is defined as the most current of (i) the last sale price disseminated during the Regular Market Session on the current trade date; (ii) last trade price disseminated outside of the Regular Market Session (Form T, as communicated by the relevant SIP) on trade date which other than for the Form T designation would have been considered a valid last sale price; or (iii) if neither of the prices above are available, the prior days Official Closing Price from the listing exchange, adjusted to account for corporate actions, news events, etc. In the event there is no valid Order Collar Reference Price or Router Constraint Reference Price, the Exchange generally rejects orders for the security.

[16] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012). Note, unless otherwise specified, capitalized terms used in reference to the LULD Plan have the same meaning as set forth in the LULD Plan or in Exchange rules. *See also* Rule 11.280(e)(Limit Up-Limit Down Mechanism), which sets forth the Exchange's methodology for re-pricing and canceling interest pursuant to the LULD Plan.

[17] 17 CFR 242.201. *See also* Rule 11.190(h)(4)(Short Sale Price Sliding).

[18] Pursuant to Rule 11.190(b)(9), upon entry and on Book Recheck, Midpoint Peg orders attempt to remove all available liquidity at the less aggressive of the Midpoint Price or the orders limit price, if any.

[19] Pursuant to Rule 11.190(b)(10), upon entry and on Book Recheck, Discretionary Peg orders attempt to remove all available liquidity at the less aggressive of the Midpoint Price or the orders limit price, if any.

[20] Pursuant to Rule 11.190(b)(8), upon entry, Primary Peg orders attempt to remove liquidity at the less aggressive of one (1) MPV less aggressive than the NBB (NBO) for buy (sell) orders or the orders limit price, if any. Therefore, because the System will not generate an internally locked or crossed book (as a result of execution and price sliding logic, including the Exchange's price sliding processes for non-displayed orders (the ''Midpoint Price Constraint''), which restricts non-displayed orders from resting on the Order Book at a price more aggressive than the midpoint of the NBBO, Primary Peg orders Primary Peg orders are never eligible to remove liquidity. Accordingly, Primary Peg orders are not eligible for Book Recheck.

[21] Generally, if the current NBB for a covered security decreased by 10% or more from the security's closing price as determined by the listing market, Rule 201 of Regulation SHO prohibits the execution or display of a short sale order not marked short exempt at a price that is less than or equal to the NBB. *See* 17 CFR 242.201.

[22] To continue to this example, if the Exchange has non-displayed liquidity to buy resting on the Order Book at $10.11, a short sale order not marked short exempt would be eligible to remove such interest upon entry (or, if such interest was entered after the short sale order, on Book Recheck), but would not receive the Spread-Crossing Remove Fee, because such order is not executable at the NBB.

$10.10, and IEX has a displayed offer at $10.10, a limit order to buy with a limit price of $10.10 or higher that removes liquidity will receive the Spread-Crossing Remove Fee. While the Exchange believes the arbitrage opportunity provides a natural incentive for market participants to resolve the crossing quotation, the Exchange intends to further incentivize such market improving behavior by charging such removers the proposed Spread-Crossing Remove Fee.

The Exchange notes that executions subject to the Crumbling Quote Remove Fee are not eligible for the Spread-Crossing Remove Fee.[23] Accordingly, transactions that are subject to the Crumbling Quote Remove Fee that remove liquidity with an order executable at the far side of the NBBO will be charged the Crumbling Quote Remove Fee, rather than the Spread-Crossing Remove Fee. Furthermore, the Exchange is not proposing any change to the Internalization Fee whereby no fee is charged for executions when the adding and removing order originated from the same Exchange Member. Thus, transactions that qualify for the Internalization Fee and the proposed Spread-Crossing Remove Fee will be charged the Internalization Fee rather than the Spread-Crossing Remove Fee, since the IEX Fee Schedule provides that to the extent a Member receives multiple Fee Codes on an execution, the lower fee shall apply.[24]

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)[25] of the Act in general, and furthers the objectives of Sections 6(b)(4)[26] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange believes that the proposed fee change is reasonable, fair and equitable, and non-discriminatory. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive.

As proposed, the Spread-Crossing Remove Fee is designed to reduce the variability in fees to access liquidity on the Exchange, therefore making the Exchange's Fee Schedule more clear and predictable to the benefit of all market participants. Furthermore, as discussed in the Purpose section, the Exchange believes that to the extent the proposed Spread-Crossing Remove Fee incentivizes additional spread-crossing orders on the Exchange, resting displayed interest will have enhanced opportunities to capture the spread, which may result in additional aggressively priced orders being entered on the Exchange, thereby contributing to public price discovery, consistent with the overall goal of enhancing market quality.

The Exchange does not believe that the proposed change represents a significant departure from pricing currently offered by the Exchange. As described in the Purpose section, the proposed Spread-Crossing Remove Fee is equal to the Displayed Match Fee, and less than the Non-Displayed Match Fee, thus falling within the range of transaction fees currently charged by the Exchange. Furthermore, the proposed Spread-Crossing Remove Fee is substantially lower than the fee for removing liquidity on competing exchanges with a ''maker-taker'' fee structure (*i.e.,* that provide a rebate to liquidity adders and charge liquidity removers).[27]

As proposed, Members that remove non-displayed liquidity on the Exchange will be charged disparate fees depending on whether or not the removing order was executable at the far side of the NBBO. For example, a limit order with a User-defined and system-adjusted limit price that is marketable to the Midpoint Price that removes non-displayed liquidity at the Midpoint Price will be charged the Non-Displayed Match Fee, whereas a limit order with a User-defined and system-adjusted limit price that is executable at the far side of the NBBO that removes non-displayed liquidity at the Midpoint Price will be charged the Spread-Crossing Remove Fee. The Exchange believes it is reasonable, equitable and not unfairly discriminatory to charge disparate fees for removing liquidity on the Exchange depending on whether or not the removing order was executable at the far side of the NBBO, because spread-crossing orders are willing to interact with the Exchange's resting displayed orders, thereby potentially incentivizing Members to enter more aggressively priced displayed orders by enhancing opportunities for such orders to capture the full spread.

The Exchange believes incentivizing market makers and other Members to enter more aggressively priced displayed orders on the Exchange by enhancing trading opportunities at the NBBO significantly contributes to public price discovery, consistent with the overall goal of enhancing market quality. Furthermore, removers of non-displayed liquidity that are not willing to cross the spread are receiving the benefit of trading more passively and receiving price improvement, which the Exchange believes is a substantial incentive and benefit in and of itself.[28] Similarly, non-displayed orders resting on the Exchange are receiving the benefit of resting passively on the Order Book and capturing the spread in whole or in part. Therefore, the Exchange believes it is reasonable, equitable and not unfairly discriminatory to charge Members that add non-displayed liquidity a different fee then Members that remove non-displayed liquidity with an order that is executable at the far side of the NBBO.[29]

[23] *See* Fee Code Q (Crumbling Quote Remove Fee Indicator), along with the footnote appurtenant thereto in the Investors Exchange Fee Schedule, available on the Exchange public website, which together describe the applicable fee for executions that take liquidity during periods of quote instability as defined in Rule 11.190(g) that exceed the CQRF Threshold, which is equal to is equal to 5% of the sum of a Member's total monthly executions on IEX if at least 1,000,000 shares during the calendar month, measured on an MPID basis. See also Securities and Exchange Act Release No. 81484 (August 25, 2017) 82 FR 41446 (August 31, 2017) (SR–IEX–2017–27). *See also* footnote three under Transaction Fees in the Investors Exchange Fee Schedule, which specifies that, except for the Crumbling Quote Remove Fee Code of Q, to the extent a Member receives multiple Fee Codes on an execution, the lower fee shall apply.

[24] *See* footnote three under Transaction Fees in the Investors Exchange Fee Schedule, which specifies that, except for the Crumbling Quote Remove Fee Code of Q, to the extent a Member receives multiple Fee Codes on an execution, the lower fee shall apply.

[25] 15 U.S.C. 78f.

[26] 15 U.S.C. 78f(b)(4).

[27] *See, e.g.,* the New York Stock Exchange (''NYSE'') trading fee schedule on its public website reflects fees to ''take'' liquidity ranging from $0.0024–$0.0030 depending on the type of market participant, order and execution; the Nasdaq Stock Market (''Nasdaq'') trading fee schedule on its public website reflects fees to ''remove'' liquidity ranging from $0.0025–$0.0030 per share for shares executed in continuous trading at or above $1.00 or 0.30% of total dollar volume for shares executed below $1.00; the Cboe BZX Exchange (''Cboe BZX'') trading fee schedule on its public website reflects fees for ''removing'' liquidity ranging from $0.0025–$0.0030, for shares executed in continuous trading at or above $1.00 or 0.30% of total dollar volume for shares executed below $1.00.

[28] The Exchange notes the spread-crossing removers may also receive such price improvement to the extent they remove non-displayed liquidity resting within the spread. However, such price improvement is not guaranteed, and spread-crossing removers consciously choose to pay the full spread with only the possibility of price improvement.

[29] The Exchange also notes that it is common for Exchange's to charge Members different fees for adding and removing liquidity, and thus the Exchange's proposal is not novel in this regard. *See, e.g.,* the New York Stock Exchange (''NYSE'') trading fee schedule on its public website which reflects fees to ''take'' liquidity ranging from $0.0024–$0.0030 depending on the type of market participant, order and execution. Additionally,

Continued

The Exchange also believes that it is reasonable, fair and equitable, and non-discriminatory to not offer the proposed Spread-Crossing Remove Fee to orders that are subject to the Crumbling Quote Remove Fee because such executions are necessarily a part of a trading strategy that the Exchange believes evidences a form of predatory latency arbitrage that leverages low latency proprietary market data feeds and connectivity along with predictive models to chase short-term price momentum and successfully target resting orders at unstable prices. Furthermore, if the Exchange were to apply the Spread-Crossing Remove Fee to executions that are subject to the Crumbling Quote Remove Fee, it would frustrate its fundamental purpose of disincentivizing predatory trading strategies to further incentivize additional resting liquidity, including displayed liquidity, on IEX. Thus, a Member that removes liquidity with spread-crossing orders that are subject to the Crumbling Quote Remove Fee, should not be afforded the benefit of the proposed Spread-Crossing Remove Fee on such executions.

The Exchange also notes that the Crumbling Quote Remove Fee, in combination with the proposed Spread-Crossing Remove Fee, is designed to incentivize spread-crossing interest that is not part of what the Exchange believes is a predatory trading strategy, therefore potentially increasing the entry of orders executable at the far side of the NBBO during periods of relative market stability. If the Spread-Crossing Remove Fee is successful in this regard, the opportunity for execution and the resultant execution performance for non-displayed resting orders within the spread, as well as displayed orders resting at the NBBO, would be significantly enhanced. Consequently, enhanced trading opportunities may incentivize the entry of non-displayed orders resting at or within the spread, as well as displayed order resting at the NBBO, thereby contributing to the post-trade and pre-trade public price discovery process, respectively. Accordingly, the Exchange believes that the Crumbling Quote Remove Fee, in combination with the proposed Spread-Crossing Remove Fee, is reasonable, fair and equitable, and non-discriminatory.

Additionally, the Exchange believes that it is reasonable, fair and equitable, and non-discriminatory to continue to charge the Internalization Fee rather than the Spread-Crossing Remove Fee when the adding and removing order originated from the same Exchange Member. IEX believes that the same factors that support not charging fees for such transactions, as described in its rule filing adopting this fee structure, continue to be relevant.[30] Specifically, not charging a fee is designed to incentivize Members (and their customers) to send orders to IEX that may otherwise be internalized off exchange, with the goal of increasing order interaction on IEX. Internalization on IEX is not guaranteed, and the additional order flow that does not internalize is available to trade by all Members.

Finally, the Exchange believes that the proposed fees are nondiscriminatory because they will apply uniformly to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if fee schedules at other venues are viewed as more favorable. Consequently, the Exchange believes that the degree to which IEX fees could impose any burden on competition is extremely limited and does not believe that such fees would burden competition between Members or competing venues in a manner that is not necessary or appropriate in furtherance of the purposes of the Act. Moreover, as noted in the Statutory Basis section, the Exchange does not believe that the proposed changes represent a significant departure from its current fee structure, and competing venues are able to adopt comparable pricing.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different fees are assessed in some circumstances, these different fees are not based on the type of Member entering the orders that match but on the type of order entered and the market conditions in which such order was entered. Moreover, the proposed Spread-Crossing Remove Fee will apply equally to all Members that remove liquidity with an order executable at the far side of the NBBO. The Exchange notes that all Members can submit any of the Exchange's approved order types and order parameters, including orders that are executable at the far side of the NBBO. Further, the proposed fee changes continue to be intended to encourage market participants to bring increased order flow to the Exchange, which benefits all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) [31] of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [32] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–IEX–2018–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

NYSE fees to ''add'' liquidity range from $0.0018–$0.0030 per share for shares executed in continuous trading; [sic]

[30] *See* Securities Exchange Act Release No. 78550 (August 11, 2016), 81 FR 54873 (August 17, 2016) (SR–IEX–2016–09).

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

[32] 15 U.S.C. 78s(b)(2)(B).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–IEX–2018–09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–IEX–2018–09, and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09577 Filed 5–4–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83143; File No. SR–CHX–2018–001]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Designation of a Longer Period on Commission Action on a Proposed Rule Change To Adopt the Route QCT Cross Routing Option

May 1, 2018.

On March 6, 2018, the Chicago Stock Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b-4 thereunder,[2] a proposed rule change to adopt the Route QCT Cross routing option. The proposed rule change was published for comment in the **Federal Register** on March 20, 2018.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is May 4, 2018. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider this proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates June 18, 2018, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–CHX–2018–001).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09573 Filed 5–4–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83141; File No. SR–Phlx–2018–32]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Market Order Spread Protection

May 1, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 20, 2018, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt a new Market Order Spread Protection.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this rule change is to adopt a new Market Order Spread Protection rule similar to The Nasdaq

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 82870 (March 14, 2018), 83 FR 12214.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Options Market LLC (''NOM'').[3] The Exchange also proposes an amendment to Rule 1099, entitled ''Order Protections.''

Today, Phlx Rule 1099 includes various order protections which apply only to simple orders. The Exchange is proposing to amend Rule 1099 to include rule text which makes clear that the order protections within Rule 1099 apply only to simple orders. Further, the Exchange proposes to adopt Market Order Spread Protection functionality within Rule 1099(d), which protection would similarly apply only to simple orders.

This new mandatory risk protection entitled Market Order Spread Protection protects Market Orders [4] from being executed in very wide markets. This feature would be set at the same preset threshold [5] for all options traded on Phlx. The proposed new rule provides that a Market Order will be rejected if the best of the NBBO and the internal market PBBO [6] is wider than a preset threshold, which is selected by the Exchange and announced to members, at the time the Market Order is received by the System. NOM has two non-displayed order types, Price-Improving and Post-Only Orders, which may cause the order book on NOM to be better than the NBBO. Phlx similarly has non-displayed order types, all-or-none,[7] stop orders [8] and legging orders [9] (collectively ''Non-Displayed Orders''). These Non-Displayed Orders may cause the order book on Phlx to be better than the NBBO. The Exchange also notes that orders which lock or cross another market [10] will cause the PBBO to reprice and also could result in the internal market PBBO being better than the NBBO. The Exchange notes that Non-Displayed Orders would be considered when validating orders on entry for the proposed Market Order Spread Protection, except for all-or-none orders. All-or-none orders have a quantity contingency requiring the full quantity of the order to execute in order for any trade to take place, which may cause the order to not execute. If an all-or-none contingency cannot be met, the all-or-none order would be bypassed until such time as the contingency could be met. For this reason, an all-or-none order will not be considered during the validation of orders on entry for purposes of Market Order Spread Protection. Below are some examples:

Example No. 1

If the Market Order Spread Protection threshold is set to $5.00, and a Market Order to buy is received while the NBBO and internal PBBO are both $1.00–$6.05 and there are no Non-Displayed Orders resting on the book, such Market Order will be rejected. . [sic]

Example No. 2

The following is an example of how a legging order interacts with the Market Order Spread Protection. Assume an option minimum price increment (MPV) is scaled in $0.05 increments and a limit buy order of $0.05 exists on the Exchange. If the system generates a legging order to sell at $ 0.11, this order will not be displayed at its limit of $0.11, because the order is priced at a non-MPV increment. This order will be displayed at the nearest MPV price of $0.15 (because of the option's $0.05 MPV increment). Thus, the displayed spread is $0.10; however the PBBO is $0.06. Assume this order makes up the best offer on the Exchange. For this example, assume the Market Order Spread Threshold in the System is set at $ 0.09. Further assume a Market Order to buy is submitted to the Exchange. Based on the Exchange's proposed implementation of Market Order Spread Protection, the Market Order to buy would execute against the resting sell order at $0.11, since $0.11 is the best available offer and the internal market PBBO spread is $0.06 (spread between the best bid of $0.05 and the best offer of $ 0.11) which is less than the Market Order Spread Threshold of $0.09.

Example No. 3

The following is an example of how an all-or-none order interacts with Market Order Spread Protection. Assume an NBBO: 0×5.50 and a PBBO of 0×5.45. Also assume an all-or-none order is resting in the order book to sell 1000 at 4.95 and an incoming Market Order to buy 10. The all-or-none order would not be considered in the validation and the incoming Market Order would be rejected. In this example, if the all-or-none order had been considered in the validation that Market Order would have executed at 5.45, an inferior price because the full quantity of the resting all-or-none order could not be satisfied.

The proposed feature would assist with the maintenance of fair and orderly markets by ensuring that the best bid and offer displayed on the Exchange are within a reasonable range and preventing market orders from trading outside of the reasonable range when the best bid and offer displayed are not within the allowable range. The Exchange proposes this feature to avoid executions of Market Orders when the market is too wide for a reasonable execution.

Today, the NOM threshold is set at $5. Phlx will initially set the threshold to $5. Similar to NOM, the Exchange will notify Members of the threshold with advanced notice to members through an Options Trader Alert, and, thereafter, members will be notified in advance of any subsequent changes to the threshold. NOM set the differential at $5 to match the bid/ask differential permitted for quotes on the Exchange.[11] The Exchange would consider a subsequent change to the threshold if it believed that the $5 initial threshold was too wide or too restrictive as between the bid and offer to create a reasonable range for executions. Phlx has the same differential.[12] Thus, the presence of a quote on the Exchange will ensure the NBBO is at least $5 wide. The Exchange believes the

[3] *See* NOM Rules at Chapter VI, Section 6(c).

[4] Market Orders are orders to buy or sell at the best price available at the time of execution.

[5] This preset threshold would initially be $5, as explained in more detail below.

[6] This is the best bid and offer on the Phlx order book including non-displayed legging and stop orders. Resting AON orders are not considered as part of the internal market PBBO in applying the Market Order Spread Protection. Resting AON orders may be passed by in allocation if the incoming order does have sufficient quantity to satisfy the resting AON.

[7] An all-or-none order is a limit or market order that is to be executed in its entirety or not at all.

[8] A stop order is a limit or market order to buy or sell at a limit price when a trade or quote on the Exchange for a particular option contract reaches a specified price. A stop-market or stop-limit order shall not be elected by a trade that is reported late or out of sequence or by a complex order trading with another complex order.

[9] A legging order is a limit order on the regular order book in an individual series that represents one leg of a two-legged Complex Order (which improves the cPBBO) that is to buy or sell an equal quantity of two options series resting on the CBOOK. Legging orders are firm orders that are included in the Exchange's displayed best bid or offer. Legging orders are not routable and are limit orders with a time-in-force of DAY, as they represent an individual component of a Complex Order. Legging orders are non-displayed orders that are automatically generated. *See* Phlx Rule 1098(f)(iii)(C).

[10] Options Order Protection and Locked and Crossed Market Rules are located at Phlx Rule 1083. In the event of a locked and crossed market, the PBBO will be repriced and displayed in accordance with Phlx Rule 1082(a)(ii)(3)(g)(v).

[11] *See* Chapter VII, Section 6(d)(ii) of NOM Rules which describes the bid/ask differentials. Options on equities (including Exchange-Traded Fund Shares), and on index options must be quoted with a difference not to exceed $5 between the bid and offer regardless of the price of the bid, including before and during the opening. However, respecting in-the-money series where the market for the underlying security is wider than $5, the bid/ask differential may be as wide as the quotation for the underlying security on the primary market. The Exchange may establish differences other than the above for one or more series or classes of options.

[12] *See* Phlx Rule 1014(c)(i)(A)(2).

presence of a quote on the Exchange, or a bid/ask differential of the NBBO, which is no more than $5 wide affords Market Orders proper protection against erroneous execution and in the event a bid/ask differential is more than $5, then a Market Order is rejected. The threshold is appropriate because it seeks to ensure that the displayed bid and offer are within reasonable ranges and do not represent erroneous prices. The protection would reject Market Orders which are outside of the parameters of the Market Order Spread Protection. The Exchange's proposed threshold is a reasonable measure to ensure prices remain within the preset threshold set by the Exchange, which will be initially set at $5. This protection will bolster the normal resilience and market behavior that persistently produces robust reference prices. This feature should create a level of protection that prevents Market Orders from entering the Order Book outside of an acceptable range for the Market Order to execute.

Finally, the Market Order Spread Protection will be the same for all options traded on the Exchange, and is applicable to all Members that submit Market Orders. The Market Order Spread Protection would not apply during the Opening Process and trading halts, similar to the manner in which it operates today on NOM. Both the Opening Process and trading halts have their own more restrictive boundaries than those proposed for the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table [13] to be determined by the Exchange.[14] The Exchange's requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is proposed at $5. As provided in Phlx Rule 1047(g), trading halts are subject to the reopening process as provided for in Phlx Rule 1017(e). The same protections noted for the Opening Process above will apply for trading halts. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Section 6(b)(5) of the Act,[16] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by mitigating risk to market participants. By adopting this mandatory risk protection, similar to NOM, the Exchange will protect market participants from the execution of erroneous Market Orders. The proposed feature would assist with the maintenance of fair and orderly markets by ensuring that the best bid and offer displayed on the Exchange are within a reasonable range and further the protection would prevent market orders from trading outside of the reasonable range when the best bid and offer displayed are not within the allowable range.

This feature should create a level of protection that prevents erroneous Market Orders from entering the Order Book and thereby reduce the negative impacts of sudden, unanticipated volatility, and serve to preserve an orderly market in a transparent and uniform manner, increase overall market confidence, and promote fair and orderly markets and the protection of investors. This feature is not optional and is applicable to all members submitting Market Orders.

Permitting the rejection of the Market Order at the better of the NBBO or Reference PBBO does not otherwise create an impediment to a free and open market because Non-Displayed Orders exist today on NOM with this same protection and provide investors the opportunity to trade at a better price than would otherwise be available, *e.g.,* inside the disseminated best bid and offer for a security, which could result in better executions for investors. The Exchange's exclusion of all-or-none orders when validating orders on entry for purposes of Market Order Spread Protection is consistent with the protection of investors and the public interest. This contingency order is already bypassed today for purposes of priority when the contingency cannot be satisfied. The Exchange notes that because all-or-none orders have a size contingency, which may cause this order type not to execute, the result of including the all-or-none order in the validation of incoming orders could result in executions at inferior prices.

The Exchange's proposal to not apply the Market Order Spread Protection during the Opening Process and during is consistent with the Act because protections exist within those mechanisms to ensure that the best bid and offer displayed on the Exchange are within a reasonable range. The Exchange's Opening Process Rule 1017 [17] and the Trading Halt Rule 1047 [18] both contain more restrictive boundaries than those proposed for the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange. The Exchange's requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is proposed at $5. As provided in Phlx Rule 1047(g), trading halts are subject to the reopening process as provided for in Phlx Rule 1017(e). The same protections noted for the Opening Process above will apply for trading halts. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed amendments do not impose an undue burden on competition because the Market Order Spread Protection will be mandatory for all market participants.

[13] The table is published on the Exchange's website at: *http://www.nasdaqtrader.com/content/phlx/phlx_systemtime.pdf.*

[14] The calculation of Quality Opening Market is based on the best bid and offer of Valid Width Quotes. The differential between the best bid and offer are compared to reach this determination. The allowable differential, as determined by the Exchange, takes into account the type of security (for example, Penny Pilot versus non-Penny Pilot issue), volatility, option premium, and liquidity. The Quality Opening Market differential is intended to ensure the price at which the Exchange opens reflects current market conditions. *See* Phlx Rule 1017(a)(viiii).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange and published on the Exchange's website. *See* Phlx Rule 1017(a)(viiii).

[18] With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply. *See* Phlx Rule 1017(e).

The Marker Order Spread Protection feature will provide market participants with additional price protection from anomalous executions. The Exchange does not believe the proposal creates any significant impact on competition.

The Exchange does not believe that accounting for Non-Displayed Orders, except for all-or-none orders, or repricing due to trade-through and locked and crossed market restrictions creates an undue burden on competition because it will serve to provide members with additional information in the rule text to anticipate the impact of the Market Order Spread Protection feature. Today, members are able to submit orders or quotes priced between the MPV for display at the nearest MPV.

The Exchange does not believe that not applying the Market Order Spread Protection during the Opening Process and during a trading halt creates an undue burden on competition because these mechanisms offer more restrictive protections than the proposed initial setting for the Market Order Spread Protection, which is proposed at $5.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [19] and subparagraph (f)(6) of Rule 19b–4 thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [21] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change will become operative on filing. The Exchange states that waiver of the 30-day operative delay would allow the Exchange to immediately offer a mandatory risk protection, similar to NOM, for all market participants transacting in simple orders to protect market participants from entering Market Orders outside of a reasonable range for execution. Based on the foregoing, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[22]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2018–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2018–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2018–32, and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09571 Filed 5–4–18; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6)(iii).

[22] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83148; File No. SR–CTA/CQ–2018–01]

Consolidated Tape Association; Order of Summary Abrogation of the Twenty-Third Charges Amendment to the Second Restatement of the CTA Plan and the Fourteenth Charges Amendment to the Restated CQ Plan

May 1, 2018.

I. Introduction

Notice is hereby given that the Securities and Exchange Commission (''Commission''), pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 608 thereunder,[2] is summarily abrogating the Twenty-Third Charges Amendment

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

to the Second Restatement of the Consolidated Tape Association (''CTA'') Plan and the Fourteenth Charges Amendment to the Restated Consolidated Quotation (''CQ'') Plan (collectively, ''Plans'').[3]

On March 5, 2018 [4] the participants of the Plans (''Participants'') [5] filed with the Commission a proposal to amend the Plans (''Amendment''), pursuant to Section 11A of the Act,[6] and Rule 608 thereunder.[7] The Amendment, which was effective upon filing pursuant to Rule 608(b)(3)(i) of Regulation NMS,[8] modified the Plans' fee schedules to adopt changes to the Broker-Dealer Enterprise Maximum Monthly Charge and Per-Quote-Packet Charges.

II. Description of the Amendment

A. Amendments to Enterprise Cap

The Amendment modified the Plans' fee schedules to increase the Broker-Dealer Enterprise Maximum Monthly Charge (''Enterprise Cap'') from $686,400 to $1,260,000 for Network A and from $520,000 to $680,000 for Network B. The Participants stated that as a result of industry consolidation, the Nonprofessional Subscriber base for entities subject to the Enterprise Cap may suddenly increase, and whereas before two entities may have benefited slightly from the Enterprise Cap, a combined entity could achieve a substantial decrease in fees by using the Enterprise Cap. Consequently, the Participants stated, the increase of the Enterprise Cap was designed to maintain the status quo and should not have, in conjunction with the Per-Quote-Packet Charges described below, resulted in an increase of revenue to the Plans or fees for any particular entity.[9]

In addition, the Amendment modified the Plans to remove a provision relating to annual increases of the Enterprise Cap after a two-thirds vote of the Participants. In 2013,[10] the Participants amended the mechanism by which the Enterprise Cap would increase, from an automatic increase based on volume, to a requirement for an affirmative vote of the Participants. The Participants have not used this mechanism to increase the Enterprise Cap. The Participants believe that any future changes to the Enterprise Cap should be filed with the Commission and subject to public comment. Consequently, the Participants proposed to delete this provision.

B. Amendments to the Per-Quote-Packet Charges

The Participants stated that because of the increase in the Enterprise Cap, there could have been broker-dealers that used the Enterprise Cap that, without a corresponding offset, could have faced an increase in fees. To offset the potential fee increase, the Amendment modified the text of the Plans' fee schedules to reduce the Plans' Per-Quote-Packet Charges for broker-dealers with 500,000 or more Nonprofessional Subscribers from $.0075 to $.0025.

The Participants stated that by implementing a tiered structure for Per-Quote-Packet Charges, the proposal was designed to provide an offset to those firms most likely affected by the Enterprise Cap increase (*i.e.,* those with a large Nonprofessional Subscriber base). Additionally, the Participants stated that the proposal would align the tiered structures for Networks A and B with those of Network C.

Pursuant to Rule 608(b)(3)(i) under Regulation NMS,[11] the Participants designated the Amendment as establishing or changing a fee or other charge collected on their behalf in connection with access to, or use of, the facilities contemplated by the Plans. As a result, the Amendment was effective upon filing with the Commission. The Amendment was published for comment in the **Federal Register** on March 29, 2018.[12]

III. Summary of Comments

The Commission received two comment letters in response to the Notice of Filing,[13] and a response thereto from the Participants.[14] Healthy Markets [15] urged the Commission to summarily abrogate the Amendment on grounds that it is not appropriately justified, is discriminatory, and is contrary to the original purpose of the Enterprise Cap. Healthy Markets also stated that the Enterprise Cap should be eliminated as part of the broader process of modernizing the CTA and CQ fee schedules.

Specifically, Healthy Markets stated that the Participants failed to support their representations regarding industry consolidation and noted that the Amendment lacks any detailed justification or analysis.[16] In addition, Healthy Markets stated that the Participants' representation that the Amendment may be revenue neutral does not demonstrate that the Amendment is consistent with the Act whose goal is to protect the public interest by, amongst other things, promoting competition, the reasonable allocation of fees, and non-discrimination.[17] Healthy Markets also argues that the Amendment is discriminatory in that it appears to target a very small segment of firms, possibly a single firm.[18] Lastly, Healthy Market stated that the Enterprise Cap should be eliminated as part of the broader process of modernizing the CTA and CQ fee schedules to simply allow for the non-discriminatory, consistent access and pricing of public market data.[19]

In its comment letter, SIFMA stated that the information provided by the Participants in the Amendment with respect to, among other things, cost, revenue, and customer data, is insufficient to permit the Commission to determine whether the Amendment is

[3] *See* Securities Exchange Act Release Nos. 10787 (May 10, 1974), 39 FR 17799 (May 20, 1974) (declaring the CTA Plan effective); 15009 (July 28, 1978), 43 FR 34851 (August 7, 1978) (temporarily authorizing the CQ Plan); and 16518 (January 22, 1980), 45 FR 6521 (January 28, 1980) (permanently authorizing the CQ Plan). The most recent restatement of both Plans was in 1995. The CTA Plan, pursuant to which markets collect and disseminate last sale price information for non-NASDAQ listed securities, is a ''transaction reporting plan'' under Rule 601 under the Act, 17 CFR 242.601, and a ''national market system plan'' under Rule 608 under the Act, 17 CFR 242.608. The CQ Plan, pursuant to which markets collect and disseminate bid/ask quotation information for listed securities, is a national market system plan.

[4] *See* Securities Exchange Act Release No. 823937 (March 23, 2018), 83 FR 13539 (March 29, 2018) (''Notice of Filing'').

[5] The Participants are: Cboe BYX Exchange; Inc.; Cboe BZX Exchange, Inc.; Cboe EDGA Exchange, Inc.; Cboe EDGX Exchange, Inc.; Chicago Board Options Exchange, Incorporated; Chicago Stock Exchange, Inc.; Financial Industry Regulatory Authority, Inc.; Investors Exchange LLC; Nasdaq BX, Inc.; Nasdaq ISE, LLC; Nasdaq PHLX LLC; The Nasdaq Stock Market LLC; New York Stock Exchange LLC; NYSE Arca, Inc.; NYSE American LLC; NYSE National, Inc.

[6] 15 U.S.C. 78k–1.

[7] 17 CFR 242.608.

[8] 17 CFR 242.608(b)(3)(i).

[9] The Participants noted that very few entities take advantage of the Enterprise Cap.

[10] *See* Securities Exchange Act Release No. 70010 (July 19, 2013), 78 FR 44984 (July 25, 2013).

[11] 17 CFR 242.608(b)(3)(i).

[12] *See* Notice of Filing, *supra* note 4.

[13] *See* letters from Tyler Gellasch, Executive Director, Healthy Markets Association (''Healthy Markets''), dated April 11, 2018 (''Healthy Markets Letter''), and Melissa MacGregor, Managing Director, Securities Industry and Financial Markets Association (''SIFMA''), dated April 19, 2018 (''SIFMA Letter''), to Brent J. Fields, Secretary, Commission.

[14] *See* Letter from Emily Kasparov to Brent J. Fields, Secretary, Commission, dated April 27, 2018 (''Participants' Response'').

[15] Healthy Markets also commented on other items that are not germane to the instant filing, such, as SR–CTA/CQ–2017–14 and broader recommendations for NMS Plans and Securities Information Processor Fees.

[16] *See* Healthy Markets Letter, *supra* note 13 at 6.

[17] *See id.* at 6–7.

[18] *See id.* at 6.

[19] *See id.* at 8.

consistent with the Act.[20] SIFMA stated that only the Participants, and not SIFMA or other market participants, possess the information necessary to evaluate the Amendment.[21] SIFMA also stated that, costs, and not revenue neutrality as the Participants suggest, is the relevant factor in assessing whether the Amendment is consistent with the Act.[22]

In response, the Participants stated that the comments received are misguided or incorrect, and require no further response from the Participants.[23] In addition, the Participants stated that market participants have access to the information necessary to assess the impact of the Amendments on revenue,[24] asserting that data subscribers can readily apply the new fee schedule to their historical usage to project future usage and thereby determine whether the Participants' representations concerning the effect on revenue hold true.[25] The Participants also noted that only industry associations commented on the Amendments, and that individual market data subscribers could have commented on the Amendments had the Participants'analysis been incorrect.[26]

IV. Discussion

Pursuant to Section 11A of the Act [27] and Rule 608(b)(3)(iii) of Regulation NMS thereunder,[28] at any time within 60 days of the filing of any such amendment, the Commission may summarily abrogate the amendment and require that the amendment be re-filed in accordance with paragraph (a)(1) of Rule 608 [29] and reviewed in accordance with paragraph (b)(2) of Rule 608,[30] if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act. The Commission is concerned that the information and justifications provided by the Participants are not sufficient for the Commission to determine whether the Amendment is consistent with the Act. Accordingly, the Commission believes that the procedures set forth in Rule 608(b)(2) [31] will provide a more appropriate mechanism for determining whether the Amendment is consistent with the Act.

The Commission believes that the Amendment raises questions as to whether the changes will result in fees that are fair and reasonable, not unreasonably discriminatory,[32] and that will not impose an undue or inappropriate burden on competition under Section 11A of the Act.[33]

The Commission does not believe that the Participants have provided sufficient information regarding, or adequate justification for, the changes described in the Amendment. While the Participants represent that they used certain data to calibrate the fee changes to achieve a revenue neutral outcome [34] none of that data is provided in the Amendment, nor do the Participants provide any such information in their response.[35] The Commission is also concerned that the Participants provided little information concerning the basis for, the anticipated revenue effects of, and the effects on market participants from, the Amendment. The Participants have not provided sufficient information for the changes to be closely scrutinized for fairness and reasonableness and the Amendment lacks support for the basis of, as well as the application and likely effect of, the fees to determine that the Amendment is not unreasonably discriminatory.

In addition, the Enterprise Cap is approximately doubled for Network A, while it is being raised by substantially less than half from $520,000 to $680,000 for Network B. The Participants have provided no justification for this difference. Similarly, the Participants did not provide information to support their assertion that the increase of the Enterprise Cap is designed to maintain the status quo and should not, in conjunction with the Per-Quote Packet fee changes, result in an increase of revenue to the Plans or of fees to any particular entity.[36] The Participants lowered the Per-Quote Packet fee for firms with at least 500,000 non-professional accounts. However, the filing does not indicate why the Participants chose to limit the lower fee to firms that have 500,000 non-professional subscribers. The Participants state that the Amendment does not impose any burden on competition that is not necessary or appropriate because the fees are revenue neutral and maintain the status quo. Because the Participants did not provide the Commission with sufficient data to support their assertion that the fee change should not result in an increase of revenue to the Plans or to fees for any particular entity, the Commission is unable to evaluate the Participants' assertions that the Amendment does not impose any burden on competition that is not necessary or appropriate.

V. Conclusion

For the reasons stated above, the Commission believes it necessary or appropriate to summarily abrogate the Amendment and terminate its status as immediately effective. The Commission believes that the procedures set forth in Rule 608(b)(2) of Regulation NMS [37] will provide a more appropriate mechanism for determining whether the Amendment is consistent with the Act. Therefore, the Commission believes that it is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act, to summarily abrogate the Amendment.

It is therefore ordered, pursuant to Section 11A of the Act,[38] and Rule 608 thereunder,[39] that the Twenty-Third Charges Amendment to the CTA Plan and the Fourteenth Charges Amendment to the Restated CQ Plan (SR–CTA/CQ–2018–01) be, and hereby is, summarily abrogated. If the Participants choose to re-file the Amendment, they must do so pursuant to Section 11A of the Act and the Amendment must be re-filed in accordance with paragraph (a)(1) of Rule 608 of Regulation NMS [40] for review in accordance with paragraph (b)(2) of Rule 608 of Regulation NMS.[41]

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[20] *See* SIFMA Letter, *supra* note 13 at 1–3. SIFMA also stated that absent data demonstrating a reasonable relationship between core data revenues and the costs of collecting and disseminating data, it is doubtful that maintaining the status quo with respect to market data fees is consistent with the Act. According to SIFMA, the governance structure for NMS plans is broken and market data fees are not restrained by competitive forces, thus maintaining the status quo with respect to market data fees could impose a burden on competition. *See id.* at 3.

[21] *See id.* at 1–3.

[22] *See id.* at 2.

[23] *See* Participants' Response, *supra* note 14 at 1–2.

[24] *See* Participants' Response, *supra* note 14 at 1.

[25] *See id.*

[26] *See id.*

[27] 15 U.S.C. 78k–1.

[28] 17 CFR 242.608.

[29] 17 CFR 242.608(a)(1).

[30] 17 CFR 242.608(b)(2).

[31] *Id.*

[32] 17 CFR 242.603(a)(1)–(2), 17 CFR 242.608, and 15 U.S.C. 78k–1(a)(1)(C).

[33] 15 U.S.C. 78k–1

[34] *See* Notice of Filing, *supra* note 4 at 13541.

[35] *See* Participants' Response, *supra* note 14.

[36] *Id.* at 13540.

[37] 17 CFR 242.608(b)(2).

[38] 15 U.S.C. 78k–1.

[39] 17 CFR 242.608.

[40] 17 CFR 242.608(a)(1).

[41] 17 CFR 242.608(b)(2).

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2018–09579 Filed 5–4–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83149; File No. S7–24–89]

Joint Industry Plan; Order of Summary Abrogation of the Forty-Second Amendment to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis

May 1, 2018.

I. Introduction

Notice is hereby given that the Securities and Exchange Commission (''Commission''), pursuant to Section 11A of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 608 thereunder,[2] is summarily abrogating the Forty-Second Amendment to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis (''Nasdaq/UTP Plan'' or ''Plan'').[3]

On March 5, 2018 [4] the participants of the Plans (''Participants'') [5] filed with the Commission a proposal to amend the Nasdaq/UTP Plan (''Amendment''), pursuant to Section 11A of the Act,[6] and Rule 608 thereunder.[7] The Amendment, which was effective upon filing pursuant to Rule 608(b)(3)(i) of Regulation NMS,[8] modified the Plan's fee schedule to adopt changes to the Nonprofessional Subscriber Enterprise Cap and Per Query Fees.

II. Description of the Amendment

A. Amendments to Enterprise Cap

The Amendment modified the Plan's fee schedule to increase the Nonprofessional Subscriber Enterprise Cap (''Enterprise Cap'') from $686,400 to $1,260,000. The Participants stated that as a result of industry consolidation, the non-professional subscriber base for entities subject to the Enterprise Cap may suddenly increase, and whereas before two entities may have benefited slightly from the Enterprise Cap, a combined entity could achieve a substantial decrease in fees by using the Enterprise Cap. Consequently, the Participants stated, the increase of the Enterprise Cap was designed to maintain the status quo and should not have, in conjunction with the Per-Query Fee change described below, resulted in an increase of revenue to the Plan or fees for any particular entity.[9]

In addition, the Amendment modified the Plan to remove a provision relating to annual increases of the Enterprise Cap after a two-thirds vote of the Participants. In 2014 [10] the Participants amended the mechanism by which the Enterprise Cap would increase, from an automatic increase based on volume, to a requirement for an affirmative vote of the Participants. The Participants have not used this mechanism to increase the Enterprise Cap. The Participants believe that any future changes to the Enterprise Cap should be filed with the Commission and subject to public comment. Consequently, the Participants proposed to delete this provision.

B. Amendments to the Per-Query Fee

The Participants stated that because of the increase in the Enterprise Cap, there could have been broker-dealers that used the Enterprise Cap that, without a corresponding offset, could have faced an increase in fees. To offset the potential fee increase, the Amendment modified the text of the Plan's fee schedule to reduce the Plan's Per-Query Fee for broker-dealers with 500,000 or more non-professional subscribers from $.0075 to $.0025.

The Participants stated that by implementing a tiered structure for Per-Query Fees, the proposal was designed to provide an offset to those firms most likely affected by the Enterprise Cap increase (*i.e.,* those with a large non-professional subscriber base). Additionally, the Participants stated that the proposal would align the tiered structures for Network C with those of Networks A and B.

Pursuant to Rule 608(b)(3)(i) under Regulation NMS,[11] the Participants designated the Amendment as establishing or changing a fee or other charge collected on their behalf in connection with access to, or use of, the facilities contemplated by the Plan. As a result, the Amendment was effective upon filing with the Commission. The Amendment was published for comment in the **Federal Register** on March 29, 2018.[12]

III. Summary of Comments

The Commission received two comment letters in response to the Notice of Filing [13] and a response thereto from the Participants.[14] In its comment letter, SIFMA stated that the information provided by the Participants in the Amendment with respect to, among other things, cost, revenue, and customer data, is insufficient to permit the Commission to determine whether the Amendment is consistent with the Act.[15] SIFMA stated that only the Participants, and not SIFMA or other market participants, possess the information necessary to

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[1] 15 U.S.C. 78k–1.

[2] 17 CFR 242.608.

[3] The Plan governs the collection, processing, and dissemination on a consolidated basis of quotation information and transaction reports in Eligible Securities for each of its Participants. This consolidated information informs investors of the current quotation and recent trade prices of Nasdaq securities. It enables investors to ascertain from one data source the current prices in all the markets trading Nasdaq securities. The Plan serves as the required transaction reporting plan for its Participants, which is a prerequisite for their trading Eligible Securities. *See* Securities Exchange Act Release No. 55647 (April 19, 2007), 72 FR 20891 (April 26, 2007).

[4] *See* Securities Exchange Act Release No. 82938 (March 23, 2018), 83 FR 13542 (March 29, 2018) (''Notice of Filing'').

[5] The Participants are: Cboe BYX Exchange; Inc.; Cboe BZX Exchange, Inc.; Cboe EDGA Exchange, Inc.; Cboe EDGX Exchange, Inc.; Chicago Board Options Exchange, Incorporated; Chicago Stock Exchange, Inc.; Financial Industry Regulatory Authority, Inc.; Investors Exchange LLC; Nasdaq BX, Inc.; Nasdaq ISE, LLC; Nasdaq PHLX LLC; The Nasdaq Stock Market LLC; New York Stock Exchange LLC; NYSE Arca, Inc.; NYSE American LLC; NYSE National, Inc.

[6] 15 U.S.C. 78k–1.

[7] 17 CFR 242.608.

[8] 17 CFR 242.608(b)(3)(i).

[9] The Participants noted that very few entities take advantage of the Enterprise Cap.

[10] *See* Securities Exchange Act Release No. 73279 (October 1, 2014), 79 FR 60522 (October 7, 2014) (describing the history of the Per-Query Fees).

[11] 17 CFR 242.608(b)(3)(i).

[12] *See* Notice of Filing, *supra* note 4.

[13] *See* letters from Melissa MacGregor, Managing Director, Securities Industry and Financial Markets Association (''SIFMA''), dated April 19, 2018 (''SIFMA Letter''), and Tyler Gellasch, Executive Director, Healthy Markets Association (''Healthy Markets''), dated April 30, 2018 (''Healthy Markets Letter''), to Brent J. Fields, Secretary, Commission.

[14] *See* Letter from Emily Kasparov to Brent J. Fields, Secretary, Commission, dated April 27, 2018 (''Participants' Response''). The Participants responded to the comments received on this Amendment, as well as on SR–CTA/CQ–2018–01, which amended the CTA/CQ plan in a parallel fashion.

[15] *See* SIFMA Letter, *supra* note 13 at 1–3. SIFMA also stated that absent data demonstrating a reasonable relationship between core data revenues and the costs of collecting and disseminating data, it is doubtful that maintaining the status quo with respect to market data fees is consistent with the Act. According to SIFMA, the governance structure for NMS plans is broken and market data fees are not restrained by competitive forces, thus maintaining the status quo with respect to market data fees could impose a burden on competition. *See id.* at 3.

evaluate the Amendment.[16] SIFMA also stated that, costs, and not revenue neutrality as the Participants suggest, is the relevant factor in assessing whether the Amendment is consistent with the Act.[17]

Healthy Markets[18] urged the Commission to summarily abrogate the Amendment on grounds that it is not appropriately justified, is discriminatory, and is contrary to the original purpose of the Enterprise Cap. Healthy Markets also stated that the Enterprise Cap should be eliminated as part of the broader process of modernizing the UTP fee schedules.

Specifically, Healthy Markets stated that the Participants failed to support their representations regarding industry consolidation and noted that the Amendment lacks any detailed justification or analysis.[19] In addition, Healthy Markets stated that the Participants' representation that the Amendment may be revenue neutral does not demonstrate that the Amendment is consistent with the Act whose goal is to protect the public interest by, amongst other things, promoting competition, the reasonable allocation of fees, and non-discrimination.[20] Healthy Markets also states that the Amendment is discriminatory, and that it adds complexity to an already complex process.[21] Lastly, Healthy Market stated that the Enterprise Cap should be eliminated as part of the broader process of modernizing the UTP fee schedules to simply allow for the non-discriminatory, consistent access and pricing of public market data.[22]

In response, the Participants stated that the comments received are misguided or incorrect, and require no further response from the Participants.[23] In addition, the Participants stated that market participants have access to the information necessary to assess the impact of the Amendment on revenue,[24] asserting that data subscribers can readily apply the new fee schedule to their historical usage to project future usage and thereby determine whether the Participants' representations concerning the effect on revenue hold true.[25] The Participants also noted that only industry associations commented on the Amendment, and that individual market data subscribers could have commented on the Amendment had the Participants' analysis been incorrect.[26]

IV. Discussion

Pursuant to Section 11A of the Act[27] and Rule 608(b)(3)(iii) of Regulation NMS thereunder,[28] at any time within 60 days of the filing of any such amendment, the Commission may summarily abrogate the amendment and require that the amendment be re-filed in accordance with paragraph (a)(1) of Rule 608[29] and reviewed in accordance with paragraph (b)(2) of Rule 608,[30] if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act. The Commission is concerned that the information and justifications provided by the Participants are not sufficient for the Commission to determine whether the Amendment is consistent with the Act. Accordingly, the Commission believes that the procedures set forth in Rule 608(b)(2)[31] will provide a more appropriate mechanism for determining whether the Amendment is consistent with the Act.

The Commission believes that the Amendment raises questions as to whether the changes will result in fees that are fair and reasonable, not unreasonably discriminatory,[32] and that will not impose an undue or inappropriate burden on competition under Section 11A of the Act.[33]

The Commission does not believe that the Participants have provided sufficient information regarding, or adequate justification for, the changes described in the Amendment. While the Participants represent that they used certain data to calibrate the fee changes to achieve a revenue neutral outcome[34] none of that data is provided in the Amendment, nor do the Participants provide any such information in their response.[35] The Commission is also concerned that the Participants provided little information concerning the basis for, the anticipated revenue effects of, and the effects on market participants from, the Amendment. The Participants have not provided sufficient information for the changes to be closely scrutinized for fairness and reasonableness and the Amendment lacks support for the basis of, as well as the application and likely effect of, the fees to determine that the Amendment is not unreasonably discriminatory.

In addition, the Participants did not provide information to support their assertion that the increase of the Enterprise Cap is designed to maintain the status quo and should not, in conjunction with the Per-Query fee changes, result in an increase of revenue to the Plan or of fees to any particular entity.[36] The Participants lowered the Per-Query fee for firms with at least 500,000 non-professional accounts. However the filing does not indicate why the Participants chose to limit the lower fee to firms that have 500,000 non-professional subscribers. The Participants state that the Amendment does not impose any burden on competition that is not necessary or appropriate because it is revenue neutral and maintains the status quo. Because the Participants did not provide the Commission with sufficient data to support their assertion that the fee change should not result in an increase of revenue to the Plan or to fees for any particular entity, however, the Commission is unable to evaluate the Participants' assertions that the Amendment does not impose any burden on competition that is not necessary or appropriate.

V. Conclusion

For the reasons stated above, the Commission believes it necessary or appropriate to summarily abrogate the Amendment and terminate its status as immediately effective. The Commission believes that the procedures set forth in Rule 608(b)(2) of Regulation NMS[37] will provide a more appropriate mechanism for determining whether the Amendment is consistent with the Act. Therefore, the Commission believes that it is necessary or appropriate in the public interest, for the protection of investors, or the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system or otherwise in furtherance of the purposes of the Act, to summarily abrogate the Amendment.

[16] *See id.* at 1–3.

[17] *See id.* at 2.

[18] Healthy Markets also commented on other items that are not germane to the instant filing, such as broader recommendations for NMS Plans and Securities Information Processor Fees.

[19] *See* Healthy Markets Letter, *supra* note 13 at 3–4.

[20] *See id.*

[21] *See id.* at 5.

[22] *See id.*

[23] *See* Participants' Response, *supra* note 14 at 1–2.

[24] *See* Participants' Response, *supra* note 14 at 1.

[25] *See id.*

[26] *See id.*

[27] 15 U.S.C. 78k–1.

[28] 17 CFR 242.608.

[29] 17 CFR 242.608(a)(1).

[30] 17 CFR 242.608(b)(2).

[31] *Id.*

[32] 17 CFR 242.603(a)(1)–(2), 17 CFR 242.608, and 15 U.S.C. 78k–1(a)(1)(C).

[33] 15 U.S.C. 78k–1

[34] *See* Notice of Filing, *supra* note 4 at 13543.

[35] *See* Participants' Response, *supra* note 14.

[36] *Id.*

[37] 17 CFR 242.608(b)(2).

It is therefore ordered, pursuant to Section 11A of the Act,[38] and Rule 608 thereunder,[39] that the Forty-Second Amendment to the Nasdaq/UTP Plan (File No. S7–24–89) be, and hereby is, summarily abrogated. If the Participants choose to re-file the Amendment, they must do so pursuant to Section 11A of the Act and the Amendment must be re-filed in accordance with paragraph (a)(1) of Rule 608 of Regulation NMS [40] for review in accordance with paragraph (b)(2) of Rule 608 of Regulation NMS.[41]

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2018–09580 Filed 5–4–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83129; File No. SR–FINRA–2018–015]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend FINRA Rule 6433 To Adopt the OTC Quotation Tier Pilot as Permanent

April 30, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 20, 2018, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities) to adopt as permanent the minimum quotation sizes for OTC equity securities currently operating on a pilot basis, scheduled to expire on June 7, 2018.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA proposes to amend Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities) (the ''Rule'') to adopt as permanent the minimum quotation sizes applicable to quotations in OTC equity securities [3] that were proposed pursuant to File No. SR–FINRA–2011–058 and implemented on a pilot basis on November 12, 2012 (''Tier Size Pilot'' or ''Pilot'').[4] The Pilot was initially approved for a one-year term, has been extended ten times, and currently is scheduled to expire on June 7, 2018.[5]

The Pilot tiers were designed to: (1) Simplify the structure of the minimum quotation sizes; (2) facilitate the display of customer limit orders under Rule 6460 (Display of Customer Limit Orders) (''limit order display rule''); and (3) expand the scope of the Rule to provide for uniform treatment of the types and sources of quotations that would be subject to the Rule.[6] FINRA believes the Pilot has resulted in its intended objectives, and particularly notes that the Pilot has yielded a significant positive result with regard to increased display of customer limit orders. At the same time, market quality measures have been neutral (*i.e.,* unchanged) or slightly positive (*i.e.,* slightly improved) overall during the Pilot, as compared to the pre-Pilot period, as discussed more fully below. Accordingly, FINRA believes it is appropriate and consistent with the Act to adopt the Pilot tier sizes on a permanent basis.

Objectives of the Pilot

FINRA Rule 6433 sets forth the minimum quotation sizes applicable to the display of quotations in OTC equity securities on any inter-dealer quotation system that permits quotation updates on a real-time basis. The Rule provides different minimum quotation sizes that apply depending upon the price level of the bid or offer in the security.

Prior to the Pilot, which has been in effect since November 12, 2012,[7] Rule

[38] 15 U.S.C. 78k–1.

[39] 17 CFR 242.608.

[40] 17 CFR 242.608(a)(1).

[41] 17 CFR 242.608(b)(2).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] An OTC equity security is an equity security that is not an ''NMS Stock'' as defined in Rule 600(b)(47) of SEC Regulation NMS; provided, however, that the term ''OTC equity security'' shall not include any Restricted Equity Security. *See* FINRA Rule 6420(f).

[4] *See* Securities Exchange Act Release No. 65568 (October 14, 2011), 76 FR 65307 (October 20, 2011) (Notice of Filing of File No. SR–FINRA–2011–058) (''Original Proposal'').

[5] *See* Securities Exchange Act Release No. 67208 (June 15, 2012), 77 FR 37458 (June 21, 2012) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Amend FINRA Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities)) (Order Approving File No. SR–FINRA–2011–058, as amended); *see also* Securities Exchange Act Release No. 70839 (November 8, 2013), 78 FR 68893 (November 15, 2013) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to November 14, 2014; File No. SR–FINRA–2013–049); Securities Exchange Act Release No. 73299 (October 3, 2014), 79 FR 61120 (October 9, 2014) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to February 13, 2015; File No. SR–FINRA–2014–041); Securities Exchange Act Release No. 74251 (February 11, 2015), 80 FR 8741 (February 18, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to May 15, 2015; File No. SR–FINRA–2015–002); Securities Exchange Act Release No. 74927 (May 12, 2015), 80 FR 28327 (May 18, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to August 14, 2015; File No. SR–FINRA–2015–010); Securities Exchange Act Release No. 75639 (August 7, 2015), 80 FR 48615 (August 13, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to December 11, 2015; File No. SR–FINRA–2015–028); Securities Exchange Act Release No. 76519 (November 24, 2015), 80 FR 75155 (December 1, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to June 10, 2016; File No. SR–FINRA–2015–051); Securities Exchange Act Release No. 77923 (May 26, 2016), 81 FR 35432 (June 2, 2016) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to December 9, 2016; File No. SR–FINRA–2016–016); Securities Exchange Act Release No. 79401 (November 25, 2016), 81 FR 86762 (December 1, 2016) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to June 9, 2017; File No. SR–FINRA–2016–044); Securities Exchange Act Release No. 80727 (May 18, 2017), 82 FR 23953 (May 24, 2017) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to December 8, 2017; File No. SR–FINRA–2017–014); Securities Exchange Act Release No. 82153 (November 22, 2017), 82 FR 56300 (November 28, 2017) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Tier Size Pilot to June 7, 2018; File No. SR–FINRA–2017–035).

[6] *See* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37458.

[7] *Regulatory Notice* 12–51 (November 2012); *see also Regulatory Notice* 12–37 (August 2012).

6433 provided for nine tier sizes that applied only to market makers' proprietary quotes. The pre-Pilot tiers ranged in price points from $0.00 through $2,500.01, and are shown below in Table 1.

TABLE 1

Price (bid or offer)	Minimum quote size (# of shares)
$0 to $0.50	5,000
$0.51 to $1.00	2,500
$1.01 to $10.00	500
$10.01 to $100.00	200
$100.01 to $200.00	100
$200.01 to $500.00	25
$500.01 to $1,000.00	10
$1,000.01 to $2,500.00	5
$2,500.01 +	1

Under the Pilot, the number of tiers was reduced from nine to six, and the tiers apply to all quotations displayed by market makers, whether representing proprietary or customer interest, as well as quotations displayed by non-market makers (*i.e.,* alternative trading systems or any other member firm).[8] The Pilot tiers ultimately adopted are shown below in Table 2.

TABLE 2

Price (bid or offer)	Minimum quote size (# of shares)
$0.0001 to $0.0999	10,000
$0.10 to $0.1999	5,000
$0.20 to $0.5099	2,500
$0.51 to $0.9999	1,000
$1.00 to $174.99	100
$175.00 +	1

The Pilot tiers simplified the tier structure by reducing the number of tiers from nine to six. In addition, for price points between $1.00 and $174.99, the Pilot established a minimum quotation size of 100 shares, which is comparable to the minimums generally applicable to quotations in securities on equity exchanges. The Pilot also revised the smallest price point from $0.00 to $0.0001 to conform to the minimum quotation increments under Rule 6434 (Minimum Pricing Increment for OTC Equity Securities).[9]

Importantly, the Pilot was designed to facilitate the display of customer limit orders under FINRA's limit order display rule, which generally requires that OTC market makers fully display better-priced customer limit orders (or same-priced customer limit orders that are at the best bid or offer and that increase the OTC market maker's size by more than a *de minimis* amount). Pursuant to the limit order display rule, OTC market makers are not required to display a customer limit order on an inter-dealer quotation system unless doing so would comply with the minimum quotation size applicable to the price of the quotation under the Rule. Therefore, although a customer limit order may otherwise have been required to be displayed under the limit order display rule—for example, because it improved price or the size (more than a *de minimis* amount)—if the order is less than the minimum quotation size prescribed by Rule 6433, the member is not required to display the order. Thus, FINRA believed that the revisions implemented by the Pilot would improve overall display of customer limit orders.

For example, because the Pilot would reduce the minimum quotation size from 2,500 to 100 shares for securities priced at or above $1.00, FINRA believed that competitively priced customer limit orders, which tend to be smaller-sized orders, would more likely be displayed and potentially yield a variety of benefits, including improved price transparency, enhanced execution of customer limit orders, and narrower spreads. In addition, in a memorandum on potential effects of the Pilot, SEC staff economists noted that enhanced visibility of customer limit orders could reduce customers' execution costs.[10]

An additional objective of the Pilot was to expand the Rule's scope to apply to all member quotations on an inter-dealer quotation system. Prior to the Pilot, the Rule applied only to market makers' proprietary quotes in OTC equity securities on an inter-dealer quotation system. Under the Pilot, the minimum tier sizes apply to any member quotations entered on an inter-dealer quotation system (including quotes representing customer interest and quotations entered by non-market makers).

Concerns Raised During the Proposal Process and Data Commitment

The Commission received several comments in response to FINRA's Tier Size Pilot proposal. Commenters generally were supportive of the goal of increased customer limit order display;[11] however, commenters also raised concerns regarding the impact of revised tiers. Specifically, certain commenters questioned whether the Pilot might harm market quality by permitting market makers to post quotes representing minimum dollar value commitments that are not financially meaningful, or otherwise eroding market maker liquidity in OTC equity securities.[12] In addition, some commenters believed that there was not sufficient data analysis to support the proposed changes to the tier sizes.[13]

In response to commenters' concerns, FINRA filed Amendment No. 1 to the Original Proposal to increase the minimum quotation sizes for most price points between $0.02 and $1.00, and proposed that the revised tiers operate as a one-year pilot instead of as a permanent amendment. FINRA also submitted Amendment No. 2 to the Original Proposal to, among other things, specify the items of data that FINRA would collect and provide to the Commission during the duration of the Pilot; specifically:

1. The price of the first trade of each trading day executed at or after 9:30:00 a.m., based on execution time.
2. The price of the last trade of each trading day executed at or before 4:00:00 p.m., based on execution time.
3. Daily share volume.
4. Daily dollar volume.
5. Number of limit orders from customers and in total.
6. Percentage of the day that the size of the BBO equals the minimum quote size.
7. Number of market makers actively quoting.
8. Number of executions from a limit order and number of limit orders at the BBO or better by tier size from a customer and in total.
9. Liquidity/BBO metrics
a. Time-weighted quoted spread.
b. Effective spread.
c. Time-weighted quoted depth (number of shares) at the inside.

[8] FINRA initially proposed six tiers, some of which were different from those ultimately adopted. However, in response to comments received, FINRA amended the filing to increase the minimum quotation size for most price points between $0.02 and $1.00. FINRA stated that the amended tiers were intended to facilitate the display of additional liquidity by market makers. *See* Securities Exchange Act Release No. 66819 (April 17, 2012), 77 FR 23770 (April 20, 2012) (Amendment No. 1 to File No. SR–FINRA–2011–058); *see also* Original Proposal.

[9] Rule 6434, among other things, prohibits members from displaying a bid or offer in an OTC equity security in an increment smaller than $0.01 if the bid or offer is priced $1.00 or greater per share, or in an increment smaller than $0.0001 if the bid or offer is priced below $1.00.

[10] *See* Memorandum to File No. SR–FINRA–2011–058 re: FINRA Proposal to Reduce Minimum Quotation Size in OTC Market Tiers from Division of Risk, Strategy, and Financial Innovation, dated June 1, 2012, available at: *http://www.sec.gov/comments/sr-finra-2011-058/finra2011058-13.pdf.*

[11] *See* Order Approving File No. SR–FINRA–2011–058.

[12] *See id.*

[13] *See id.* at 37461–62.

d. Time-weighted quoted depth (dollar value of shares) at the inside.

FINRA also committed to submitting an assessment, at least 60 days before the end of the Pilot, that addressed the impact of the Pilot, the concerns raised by commenters during the rule filing process, and whether the Pilot resulted in the desired effects.[14]

Pilot Assessment

FINRA submitted its assessment on the operation of the Tier Size Pilot on September 13, 2013, which utilized pilot data covering the period from November 12, 2012 through June 30, 2013.[15] The 2013 Assessment, discussed in greater detail below, included a recommendation, based on the extensive analysis conducted, that the Pilot tiers be adopted as permanent. Nonetheless, FINRA extended the Pilot duration to allow the effects of the Pilot to be more thoroughly reviewed.[16] During this extension, the Staff of the Division of Economic and Risk Analysis (''DERA'') of the SEC conducted a study, which assessed the impact of the Pilot on liquidity. The study was published as a memorandum to file (''DERA Memo to File'').[17] And while the two studies covered different time periods and employed different methods, the DERA Memo to File reported findings consistent with those of the FINRA 2013 Assessment. In light of the 2013 Assessment, FINRA's further observations, and the DERA Memo to File, FINRA continues to believe that it is appropriate to permanently adopt the tier sizes that have been in operation since November 12, 2012, and is proposing to do so at this time.

FINRA believes the 2013 Assessment demonstrated that the Pilot accomplished its objectives, including increased customer limit order display, and that key market quality indicators have been unchanged or have slightly improved overall. FINRA continued to collect and provide Pilot data to the SEC since the 2013 Assessment. In addition, FINRA has continued to monitor the impact of the operation of the Pilot on market quality metrics for the over-the-counter marketplace, which FINRA generally believes indicate positive trends overall, providing continued support for permanent adoption of the Pilot tiers.[18] Moreover, the DERA Memo to File provided further evidence, in a regression framework, that supports the conclusion that the Pilot had a neutral to positive impact on market quality.

Specifically, FINRA believes that the 2013 Assessment demonstrated that the Pilot has resulted in a meaningful increase in the display of customer limit orders. Moreover, FINRA believes the data collected during the Pilot also supports that market quality has not been harmed, as suggested by the analysis of market quality measures such as spreads and market depth.

(A) Enhanced Customer Limit Order Display

When the Commission approved the Pilot, it recognized the potential benefits of enhancing customer limit order display. Notably, the Commission found that ''[i]n the Commission's view, FINRA's proposed revisions are designed to protect investors by revising the Rule's tier thresholds such that a larger percentage of customer limit orders are reflected in quotations for OTC equity securities, thereby potentially improving the prices at which customer limit orders will be executed, consistent with the protection of investors and the public interest.'' [19] FINRA believes the Pilot clearly has achieved the objective of increased customer limit order display.

As noted in FINRA's September 2013 Assessment, between November 1, 2012 and June 30, 2013, for all tier sizes combined, there was a 13% increase in the number of customer limit orders that met the minimum quotation sizes to be eligible for display under the Pilot tiers. FINRA also observed a significant increase in the number of customer limit orders in securities priced between $0.20 and $100.00 that became eligible for display. This trend continued through July 31, 2014. Specifically, between July 1, 2013 and July 31, 2014, FINRA observed, for all tier sizes combined, an 18.45% increase in the number of customer limit orders that met the minimum quotation sizes and, therefore, eligible for display—also with the most significant increase observed for securities priced between $0.20 and $100.00.

Tables 3 and 4 below show the percentage of customer limit orders that were equal to or greater than the minimum quotation size under both the Pilot and pre-Pilot tier sizes for the specified price ranges for the periods of November 1, 2012 through June 30, 2013, and from July 1, 2013 through July 31, 2014, respectively.

TABLE 3

[November 1, 2012 through June 30, 2013]

Price range	Pilot tier size	Customer limit orders ≥ tier size (%)	Pre-pilot tier size	Customer limit orders ≥ tier size (%)
0.0001–0.0999	10,000	78.29	5,000	86.30
0.10–0.1999	5,000	56.89	5,000	56.89
0.20–0.5099	2,500	57.35	5,000	43.30
0.51–0.9999	1,000	72.81	2,500	46.05
1.00–10.00	100	97.86	500	74.73
10.01–100.00	100	98.24	200	87.93
100.01–174.99	100	90.49	100	90.49
175.00–200.00	1	100	100	96.71
200.01–500.00	1	100	25	90.74
500.01–1,000.00	1	100	10	64.62
1,000.00–2,500.00	1	100	5	61.38

[14] *See* Amendment No. 2 to File No. SR–FINRA–2011–058, available at *http://www.finra.org/file/amendment-no-2-propose-rule-change.*

[15] FINRA engaged a third-party, Cornerstone Research, to conduct an analysis of the impact of the Pilot on OTC market quality. The 2013 assessment is part of the SEC's comment file for SR–FINRA–2011–058 and also is available on FINRA's website at: *http://www.finra.org/industry/rule-filings/sr-finra-2011-058* (''2013 Assessment'').

[16] *See supra* note 5.

[17] *See* Memorandum to File No. SR–FINRA–2011–058 re: FINRA's Pilot Program Amending Minimum Quotation Size Requirements for OTC Equity Securities from DERA, dated July 28, 2017, available at: *https://www.sec.gov/files/otc_tiersizepilot_memo.pdf.*

[18] FINRA engaged in outreach with member firms that are active in the market for OTC Equity Securities regarding the operation of the Tier Size Pilot, and the majority of those firms did not oppose the permanent adoption of the Pilot.

[19] *See* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37466. *See also* Memorandum to file from Division of Risk, Strategy, and Financial Innovation, dated June 1, 2012, *supra* note 10.

TABLE 3—Continued

[November 1, 2012 through June 30, 2013]

Price range	Pilot tier size	Customer limit orders ≥ tier size (%)	Pre-pilot tier size	Customer limit orders ≥ tier size (%)
2,500.00+	1	100	1	100.00

TABLE 4

[July 1, 2013 through July 31, 2014]

Price range	Pilot tier size	Customer limit orders ≥ tier size (%)	Pre-pilot tier size	Customer limit orders ≥ tier size (%)
0.0001–0.0999	10,000	78.29	5,000	88.70
0.10–0.1999	5,000	56.89	5,000	57.78
0.20–0.5099	2,500	57.35	5,000	42.31
0.51–0.9999	1,000	72.81	2,500	42.10
1.00–10.00	100	97.86	500	68.36
10.01–100.00	100	98.24	200	78.03
100.01–174.99	100	90.49	100	90.60
175.00–200.00	1	100	100	91.94
200.01–500.00	1	100	25	89.41
500.01–1,000.00	1	100	10	66.65
1,000.00–2,500.00	1	100	5	65.58
2,500.00+	1	100	1	100.00

As was noted in the 2013 Assessment, of the 301,628,686 customer limit orders in OTC equity securities reported to FINRA's Order Audit Trail System (''OATS'') between November 1, 2012 and June 30, 2013, over 86.6% were priced between $0.20 and $100.00. Of particular note, 58.7 million customer limit orders, or almost 20% of all customer limit orders, were priced between $1.00 and $10.00. This price range experienced an increase of almost 24% in the number of customer limit orders that met the minimum quotation size to be eligible for display under the Pilot. Further, 181.6 million customer limit orders, or over 60% of all customer limit orders, were priced between $10.01 and $100.00. This price range experienced an increase of over 10% in the number of customer limit orders that met the tier sizes and were eligible for display under the Pilot tier sizes. Consequently, the 2013 Assessment found that an additional 32 million customer limit orders priced between $1.00 and $100.00 became eligible for display during the Pilot that otherwise would not have been eligible for display.

The trends during the period since the 2013 Assessment are similar. Specifically, of the 573,973,197 customer limit orders in OTC equity securities reported to OATS between July 1, 2013 and July 31, 2014, 81.4% were priced between $0.20 and $100.00. Of particular note, 114.5 million customer limit orders, or almost 20% of all customer limit orders, were priced between $1.00 and $10.00. From July 1, 2013 through July 31, 2014, this price range experienced an increase of over 29% in the number of customer limit orders that met the minimum quotation size to be eligible for display under the Pilot than would have been eligible in the absence of the Pilot. Further, 312.1 million customer limit orders, or over 54% of all customer limit orders, were priced between $10.01 and $100.00. This price range experienced an increase of over 19% in the number of customer limit orders that met the tier sizes and were eligible for display under the Pilot tier sizes. Consequently, an additional 94.9 million customer limit orders priced between $1.00 and $100.00 became eligible for display during the Pilot between June 30, 2013 and July 31, 2014 than otherwise would have been eligible for display.

Thus, with an aggregate overall increase in displayed customer limit orders in OTC equity securities over the period from November 12, 2012 through July 31, 2014 of 16.24%, representing approximately 142 million additional orders than otherwise would have been eligible for display, FINRA believes that the impact of the Pilot on limit order display has clearly been positive, with stronger than average results concentrated in the price points ranging from $10.01 and $100.00 (the range in which the majority of all customer limit orders fell (approximately 57%)).

(B) Impact on Market Quality

When the Commission approved the Pilot, it acknowledged that the Pilot may raise issues of ''potentially competing forces''—enhanced customer limit order display on the one hand, and potential harm to OTC equity market quality (liquidity, efficiency, and volatility) on the other.[20] On balance, however, the Commission expressed the view that ''as well as increasing the number of customer limit orders eligible for display and the potential for better executions, arguments can be made that FINRA's proposal will benefit the OTC market by facilitating market making activity, narrowing spreads and increasing liquidity.'' [21]

FINRA believes that analysis of the Pilot and pre-Pilot data generally shows that the market quality measures the Commission identified—*i.e.,* market maker activity, spreads and liquidity [22]—were unchanged to slightly improved, and that, therefore, there has been an overall neutral to positive impact on OTC market quality for the

[20] *See* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37467.

[21] *See* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37467.

[22] To the extent the Commission expressed concern about volatility when it approved the Pilot, its concern was premised on the Pilot's impact on liquidity. *See, e.g.,* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37470 (''[I]f the revised tier sizes result in less activity by market makers, overall liquidity in the marketplace could decline. Such a decline could result in increased volatility and less efficient pricing for OTC equity securities.'') (internal citation omitted).

majority of tiers as compared to the pre-Pilot data.[23]

As noted in the 2013 Assessment, where minimum quotation size decreased under the Pilot, effective spreads generally remained the same or narrowed, quoted spreads narrowed, and price impact generally decreased. The 2013 Assessment also stated that some of the market quality metrics provided inconclusive results, specifically for Tier 1 securities, where the minimum quote size requirement increased. The 2013 Assessment documented that effective spreads had widened, but with no significant reduction in quoted depth.[24]

In the post-2013 Assessment period of July 1, 2013 through July 31, 2014, FINRA has observed that the number of stocks quoted in the OTC market has remained relatively constant [25] and market makers continued to provide liquidity.[26] The number of BBO quotes also significantly increased throughout 2014, the second year of the Pilot; as it generally hovered around 2 million per day during the Pre-Pilot period, but steadily increased, reaching a high of approximately 6 million per day in early 2014 and leveling off to an average of 5 million per day during the month of July 2014. The average number of trades per day was higher during the first two years of the Pilot compared to the pre-Pilot level, and more than tripled by March 2014.[27] However, trading activity appears to have leveled-off in mid-2014, albeit still at levels above the pre-Pilot trading.[28] Liquidity continued to be provided at levels greater than the minimum required depth, evidenced by executions at sizes greater than the required minimums, which enabled the execution of large trades in the OTC market. For example, for Tier 1 securities where the minimum quotation size increased, the number of trades executed above the minimum size increased by approximately 75%. While there was virtually no change in the frequency of trades above the minimum size for Tiers 2 and 3, all the other tiers experienced a positive change. Trading in sizes greater than the minimum quotation occurred infrequently in these tiers both prior to and during the pilot.

The analysis of data from the second year of the Pilot also confirms FINRA's position that the impact of the change in the minimum quotation size on the market quality metrics is generally positive. FINRA staff analyzed the change in five measures to evaluate the impact of the Pilot on market quality—time-weighted quoted spreads, volume-weighted spreads, time-weighted quoted depth at the BBO, time-weighted quoted depth around the BBO, and price impact. Time-weighted quoted spreads continued to narrow during the first two years of the Pilot and these positive changes in time-weighted quoted spreads between the pre-Pilot and the first two years of the Pilot were statistically significant for all tiers.[29] Similarly, volume-weighted spreads were unchanged (or slightly narrowed) for all tiers between the pre-Pilot period and the first two years of the Pilot when accounting for the longer Pilot period.

The displayed depth decreased slightly for most tiers, but a consideration of depth beyond the BBO demonstrated that any declines were mostly statistically insignificant across tiers in the first two years of the Pilot. FINRA believes that consideration of depth beyond the BBO is a useful additional measure for assessing market depth.

In addition, based on a data review using the same methodology as was employed for the 2013 Assessment, subsequent to the completion of the 2013 Assessment, FINRA observed that the price impact of hypothetical market orders continued to remain lower during the second year of the Pilot period than during the pre-Pilot period.[30] For example, the following two tables present the price impact for hypothetical market buy and sell orders with sizes five times larger than the minimum size requirement for each tier. The price impact associated with the hypothetical orders is estimated to have declined for all tiers, which is an indication of improved market quality. The decline is significant for all levels except for Tiers 5b and 5c (for buy trades) and Tier 1 (for sell trades).[31]

[Content of footnote 31: The t-statistic is designed to measure whether the price impact associated with a trade of a given (relative) size is different between the pre-Pilot and Pilot sample periods. The difference is tested for significance by calculating the two-sample un-pooled Student's t-statistic,

$$t = \frac{\bar{X}_1 - \bar{X}_2}{s_{\bar{X}_1 - \bar{X}_2}}, \text{ where } s_{\bar{X}_1 - \bar{X}_2} = \sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}.$$

The null hypothesis (*i.e.,* that price impact is unchanged between the two sample periods) is rejected at the 90% and 95% confidence levels, if the t-statistics are greater than 1.65 and 1.96, respectively.]

[23] FINRA notes that, from an analytical perspective, changes in market quality measures may not be attributable solely due to the Pilot, since they may also be impacted by other contemporaneous market factors.

[24] For Tier 1 securities, the DERA Memo to File finds that both quoted and effective spreads increase between the pre-Pilot period (November 14, 2011 through October 31, 2012) and the Pilot period (November 12, 2012 through November 28, 2014) covered by the analysis. However, the DERA Memo to File does not find sufficient evidence that these increases in spreads were caused by the Pilot, as spreads started to widen at least six months prior to the implementation of the Pilot.

[25] The number of stocks quoted on the OTC market remained stable at around 10,000 throughout the pre-Pilot period, and during the period covered in the 2013 Assessment and FINRA's subsequent observations (November 1, 2012 through July 31, 2014).

[26] There was an average of nine market-makers for each symbol with no significant change in the number between the pre-Pilot period, and during the period covered in the 2013 Assessment and FINRA's subsequent observations (November 1, 2012 through July 31, 2014).

[27] The daily number of trades executed during the year prior to the Pilot is estimated at approximately 75,000, and reached around 250,000 trades by the end of the first quarter in 2014.

[28] The daily average number of trades was approximately 100,000 by July 2014.

[29] For stocks in price tiers where the minimum quotation size requirement decreased, the DERA Memo to File also finds that both quoted and effective spreads decrease between the pre-Pilot period (from November 14, 2011 to October 31, 2012) and the Pilot period (November 12, 2012 to November 28, 2014) covered by the analysis. Furthermore, the DERA Memo to File's analysis suggests that these decreases in spreads may reflect causal effects of the Pilot. In contrast, for stocks in price tiers where the minimum quotation size requirement increased or remained the same, the DERA Memo to File does not find sufficient evidence that the Pilot had a causal impact on spreads.

[30] As discussed in the 2013 Assessment, the price impact of hypothetical market orders is the effective half spread for a hypothetical market ''sweep'' order of a particular size. In other words, it is an estimate of what the volume-weighted average effective half spread would have been had a market order been broken up and routed to the market makers based on price priority.

[31] [Content of footnote 31 moved to the body of the text due to **Federal Register** requirements.]

TABLE 5

[Price Impact for Hypothetical Large Market Buy Orders]

Tier	Minimum quotation size change	Number of stocks	Pre-pilot (10/2011–10/2012)	Pilot (11/2012–7/2014)	Difference	t-statistic
1	Increased	3,586	0.0055	0.0050	−0.0005	(2.60)
2	Maintained	1,254	0.0235	0.0197	−0.0038	(5.03)
3	Decreased	1,752	0.0506	0.0420	−0.0086	(6.41)
4	Decreased	1,537	0.0969	0.0810	−0.0159	(5.00)
5a	Decreased	3,038	0.3295	0.2530	−0.0765	(7.79)
5b	Decreased	2,026	1.1630	1.0661	−0.0969	(1.55)
5c	Maintained	177	4.8322	4.7906	−0.0416	(0.06)

TABLE 6

[Price Impact for Hypothetical Large Market Sell Orders]

Tier	Minimum quotation size change	Number of stocks	Pre-pilot (10/2011–10/2012)	Pilot (11/2012–7/2014)	Difference	t-statistic
1	Increased	3,931	0.0062	0.0059	−0.0003	(1.60)
2	Maintained	1,483	0.0233	0.0169	−0.0064	(3.41)
3	Decreased	1,787	0.0540	0.0311	−0.0229	(4.87)
4	Decreased	1,676	0.1214	0.0656	−0.0558	(4.95)
5a	Decreased	3,059	0.4170	0.1500	−0.2670	(6.01)
5b	Decreased	2,145	2.3563	0.4214	−1.9349	(6.79)
5c	Maintained	288	14.8135	4.2683	−10.5452	(3.13)

As noted above, the 2013 Assessment was not conclusive as to the impact of the Pilot on market quality for Tier 1 securities, the only tier where the minimum quotation size increased. For example, the 2013 Assessment indicated that the time-weighted quoted spread was unchanged for Tier 1 securities in the Pilot period. However, from June 30, 2013 to July 2014, there was a statistically significant narrowing of time-weighted quoted spreads in this tier. Evidence from the second year of the Pilot suggests that volume-weighted effective spreads and depth beyond the BBO were unchanged from pre-Pilot levels, but there was a statistically significant increase in depth at the BBO. Therefore, the updated analysis provides reliable evidence that market quality for Tier 1 securities has also improved during the Pilot.[32] The data for other tiers, however, continue to provide reliable evidence that market quality has been unchanged or slightly improved under the Pilot. Thus, because the Pilot had a demonstrable positive impact on customer limit order display, and appears to have had an overall neutral to positive impact on market quality, FINRA believes it is appropriate and in the best interest of investors to adopt the Pilot tiers as permanent.

As noted in Item 2 of this filing, because the filing would allow Rule 6433 to continue to operate without interruption, if the Commission approves the proposed rule change, the implementation date of the proposed rule change shall be the date of approval by the Commission.

(C) Alternatives Considered

In developing the proposed rule change, FINRA considered several alternatives to the proposed rule change, to ensure that it (1) simplifies the structure of the minimum quotation sizes; and (2) facilitates the display of customer limit orders under Rule 6460 (Display of Customer Limit Orders) (''limit order display rule'') without having a negative impact on market quality and the number of customer limit orders that are eligible for display. Accordingly, FINRA considered alternative price points and minimum quotation sizes in forming the tiers and evaluated the number of customer limit orders that would be eligible for display. FINRA also assessed the potential impact associated with alternative price bands across multiple sample periods, and concluded that the tier structure that was adopted under the Pilot resulted in the maximum number of customer limit orders that would be eligible for display without harming competition in the OTC equity securities market. In addition, FINRA staff revised the smallest price point to conform to the minimum quotation increments under FINRA Rule 6434 and increased the minimum quotation sizes for most price points between $0.02 and $1.00. FINRA believes that the pilot tiers continue to be appropriate and should be adopted on a permanent basis.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[33] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(11) of the Act.[34] Section 15A(b)(11) requires that FINRA rules include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange which may be distributed or published by any member or person associated with a member, and the persons to whom such quotations may be supplied.

FINRA believes that adopting the Pilot tiers as permanent would promote just and equitable principles of trade

[32] As noted in note 24, *supra,* the DERA Memo to File finds that quoted and effective spreads for Tier 1 securities increase between the pre-Pilot period of November 14, 2011 to October 31, 2012 and the Pilot period of November 12, 2012 to November 28, 2014 covered by the analysis, but it does not find sufficient evidence that these increases in spreads were caused by the Pilot.

[33] 15 U.S.C. 78*o*–3(b)(6).

[34] 15 U.S.C. 78*o*–3(b)(11).

and protect investors and the public interest. The 2013 Assessment and subsequent observations clearly demonstrate that the Pilot has resulted in increased display of customer limit orders. The 2013 Assessment found a 13% increase in the number of customer limit orders that met the minimum quotation sizes to be eligible for display across all Pilot tiers, and the updated data through July 2014 shows an even greater increase of 18.45% than otherwise would have been eligible for display. Notably, the increase in customer limit orders eligible for display was significant in tiers that make up substantial percentages of the overall volume transacted in OTC equity securities.

FINRA further believes that any concerns about market quality raised by public commenters prior to the Commission's approval of Pilot have not materialized. In fact, FINRA believes that the Pilot has had a positive impact on OTC market quality for the majority of OTC equity securities and tiers. As more fully detailed above, FINRA believes the Pilot data shows overall a slight reduction in spreads for most OTC equity securities with no negative (and perhaps a positive) impact on liquidity.

As noted previously, when the Commission approved the Pilot, it emphasized the potential benefits of increasing customer limit order display. For instance, the Commission noted that increased limit order display could potentially improve the prices at which customer limit orders will be executed, consistent with the protection of investors and the public interest.[35] The Commission also has stated its belief that greater customer limit order display could increase quote competition, narrow spreads, and increase the likelihood of price improvement for OTC equity securities.[36] The Commission had maintained a longstanding view that there are benefits to promoting customer limit order display.[37]

Accordingly, FINRA believes that the Pilot accomplished its intended objectives and realized benefits anticipated in its adoption, including greater customer limit order display. At the same time, market quality indicators during the Pilot suggest that the revised tiers and greater customer limit order display did not result in a harmful reduction in liquidity for OTC equity securities. As a result, FINRA believes it is consistent with the Act to adopt the Pilot tiers as permanent.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Despite some initial concerns from commenters that the Pilot may have negative effects on market makers who quote OTC equity securities, as the Pilot has progressed, FINRA observed an overall increase in the number of market makers quoting OTC equity securities across the duration of the Pilot. Accordingly, given the increase in the number of market makers quoting OTC equity securities, as demonstrated by the analysis using the first two years of data from the Pilot, and the increased display of customer limit orders, FINRA believes the Pilot has generated evidence that support the Commission's preliminary view ''that the [Pilot] could enhance competition.'' [38]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2018–015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2018–015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2018–015 and should be submitted on or before May 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–09612 Filed 5–4–18; 8:45 am]

BILLING CODE 8011–01–P

[35] *See* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37466.

[36] *See id.* at 37469.

[37] *See id.* at 37469 n.168 (citing, among other things, the Commission's 1996 Order Handling Rules Release).

[38] *See* Order Approving File No. SR–FINRA–2011–058, 77 FR at 37469.

[39] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Military Reservist Economic Injury Disaster Loans Interest Rate for Third Quarter FY 2018

The Small Business Administration publishes an interest rate for Military Reservist Economic Injury Disaster Loans (13 CFR 123.512) on a quarterly basis. The rate will be 3.610 for loans approved on or after May 1, 2018.

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–09620 Filed 5–4–18; 8:45 am]

BILLING CODE P

SURFACE TRANSPORTATION BOARD

Release of Waybill Data

The Surface Transportation Board has received a joint request from the Illinois Department of Transportation and the Missouri Department of Transportation (WB18–15—4/13/18) for permission to use data from the Board's 2014–2016 Masked Carload Waybill Samples. A copy of this request may be obtained from the Office of Economics.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Alexander Dusenberry, (202) 245–0319.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–09641 Filed 5–4–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Open Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee Meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, notice is hereby given of a meeting of the Commercial Space Transportation Advisory Committee (COMSTAC).

DATES AND ADDRESSES: The meeting will take place on Thursday, June 14th from 10:00 a.m. to 5:00 p.m. in the atrium of the Department of Transportation Headquarters, located at 1200 New Jersey Ave SE, Washington, DC 20590. Guests should allow time for security screening when entering the building.

SUPPLEMENTARY INFORMATION: This will be the 65th meeting of the COMSTAC. The preliminary schedule for the COMSTAC meetings on June 14th is below:

—Arrival and Check-in at DOT HQ (9:30–10:00 a.m.)
—Remarks from Invited Guests (10:00 a.m.–12:00 p.m.)
—Lunch Break (12:00–1:30 p.m.)
—Committee Business and Public Comments (1:30–5:00 p.m.)

The invited guest speakers will discuss issues and topics relevant to the commercial space transportation industry, such as Congressional activity, and updates from the FAA, NASA, and National Space Council.

This meeting is open to the public. Interested members of the public may submit relevant written statements for the COMSTAC members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above and/or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should contact the points of contact listed below in writing (mail or email) by May 31st so that the information can be made available to COMSTAC members for their review and consideration before the June 14th meeting. Written statements should be supplied in the following formats: one hard copy with original signature and/or one electronic copy via email. Portable Document Format (PDF) attachments are preferred for email submissions.

An agenda will be posted on the FAA website at *www.faa.gov/go/ast.* For specific information concerning the times and locations of the COMSTAC working group meetings, contact the contact person listed below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Di Reimold, COMSTAC Executive Director; telephone (202) 267–7635; email *dorothy.reimold@faa.gov,* and Nate McIntyre, COMSTAC Designated Federal Officer; telephone (202) 267–8464; email *nathanael.mcintyre@faa.gov;* FAA Office of Commercial Space Transportation, 800 Independence Avenue SW, Room 331, Washington, DC 20591.

Complete information regarding COMSTAC is available on the FAA website at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/.*

Issued in Washington DC, May 1, 2018.

Kelvin B. Coleman,

Acting Associate Administrator for Commercial Space Transportation.

[FR Doc. 2018–09675 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2018–44]

Petition for Exemption; Summary of Petition Received; Ameriflight

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 29, 2018.

ADDRESSES: Send comments identified by docket number FAA–2014–0278 using any of the following methods:

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

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the

public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT: Clarence Garden (202) 267–7489, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Lirio Liu,

Executive Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0278.

Petitioner: Ameriflight.

Section(s) of 14 CFR Affected: 135.243(c)(2).

Description of Relief Sought: Ameriflight, LLC seeks relief to allow an incremental reduction of the current 14 CFR 135.243(c)(2) 1,200 hour minimum flight time requirement for pilots in command of aircraft under instrument flight rules (IFR), to 1,000 flight hours provided specific operational restrictions, training using a ''cockpit procedures trainer''. Additional checking, operating experience under the supervision of an instructor, and monitoring requirements are complied with as necessary to ensure an equivalent level of safety. The relief would apply exclusively to pilots in command engaged in Ameriflight, LLC cargo-only operations conducted under 14 CFR part 135 in propeller-powered airplanes that do not require a type rating.

[FR Doc. 2018–09608 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket Number DOT–OST–2017–0043

Agency Information Collection Activity; Notice of Request for Approval To Collect New Information: Oil and Gas Industry Safety Data Program

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), U.S. Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the requirements of section 3506(c)(2)(A) of Title 44 of the U.S. Code (Pub. L. 104–13, the Paperwork Reduction Act of 1995), this notice announces the intention of BTS to request the Office of Management and Budget (OMB) to approve a new data collection: Oil and Gas Industry Safety Data.

In August 2013, the Bureau of Safety and Environmental Enforcement (BSEE) and BTS signed an Interagency Agreement to develop and implement SafeOCS, a voluntary program for confidential reporting of 'near misses' occurring on the Outer Continental Shelf (OCS). The Oil and Gas Industry Safety Data (ISD) program, is a component of BTS's SafeOCS data sharing framework, that provides a trusted, proactive means for the oil and gas industry to report sensitive and proprietary safety information, and to identify early warnings of safety problems and potential safety issues by uncovering hidden, at-risk conditions not previously exposed from analysis of reportable accidents and incidents. Companies participating in the ISD are voluntarily submitting safety data. There is no regulatory requirement to submit such data.

The ISD identifies a broader range of data categories to ensure safe performance and appropriate risk management, which adds a learning component to assist the oil and gas industry in achieving improved safety performance. BTS will be the repository for the data, and will analyze and aggregate information proffered under this program, and publish reports providing identification of potential causal factors and trends or patterns before safety is compromised, and affording continuous improvement opportunities by focusing on repairing impediments to safety.

DATES: Written comments should be submitted by July 6, 2018.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments by only one of the following methods:

- *Federal e-Rulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically. Docket Number: DOT–OST–2017–0043.
- *Mail:* Docket Services, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to mail address above between 9 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Identify all transmissions with ''Docket Number DOT–OST–2017–0043'' at the beginning of each page of the document.

Instructions: All comments must include the agency name and docket number for this notice. Paper comments should be submitted in duplicate. The Docket Management Facility is open for examination and copying, at the above address from 9 a.m. to 5 p.m. EST, Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on Docket Number DOT–OST–2017–0043.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Please note that all comments received including any personal information, will be posted and will be publicly viewable, without change, at *www.regulations.gov*. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Demetra V. Collia, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation, Office of Statistical and Economic Analysis, RTS–31, E36–302, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; Phone No. (202) 366–1610; Fax No. (202) 366–3383; email: *demetra.collia@dot.gov.* Office hours are from 8:30 a.m. to 5

p.m., EST, Monday through Friday, except Federal holidays.

Data Confidentiality Provisions: The confidentiality of oil and gas industry safety data information submitted to BTS is protected under the BTS confidentiality statute (49 U.S.C. 6307) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002 (Pub. L. 107–347, Title V). In accordance with these confidentiality statutes, only statistical (aggregated) and non-identifying data will be made publicly available by BTS through its reports. BTS will not release to BSEE or any other public or private entity any information that might reveal the identity of individuals or organizations mentioned in failure notices or reports without explicit consent of the respondent and any other affected entities.

SUPPLEMENTARY INFORMATION:

I. The Data Collection

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; as amended) and 5 CFR part 1320 require each Federal agency to obtain OMB approval to initiate an information collection activity. BTS is seeking OMB approval to collect the following new data:

Title: Oil and Gas Industry Safety Data (ISD) Program.

OMB Control Number:

Type of Review: Approval of data collection. This information collection for Oil and Gas Industry Safety Data is to ensure the safe performance and appropriate risk management within the oil and gas industry, including but not limited to exploration and production.

Respondents: Oil and gas industry companies involved in the exploration and/or production working in the Gulf of Mexico (GOM). Responsibility for establishing the actual scope and burden for this collection resides with BTS.

Number of Potential Responses: One hundred.

Estimated Time per Response: 40 hours.

Frequency: Annual.

Total Annual Burden: 400 hours.

Abstract: The Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (44 U.S.C. 3501 note), can provide strong confidentiality protection for information acquired for statistical purposes under a pledge of confidentiality. CIPSEA Guidance from the Office of Management and Budget advises that a non-statistical agency or unit (BSEE) that wishes to acquire information with CIPSEA protection, may consider entering an agreement with a Federal statistical agency or unit (BTS). BTS and BSEE have determined that it is in the public interest to collect, and process ISD reports and any other data deemed necessary to administer the Oil and Gas Industry Safety Data Program under a pledge of confidentiality for statistical purposes only.

Working with subject matter experts BTS will then aggregate and further analyze these reports to identify potential causal factors and trends. All data reviewers would be subject to non-disclosure requirements mandated by CIPSEA. The results of these aggregated analyses will be distributed by BTS through public reports, workshops, and other forms. Periodic industry workshops may be scheduled by BSEE/industry to discuss the data analysis and trend results, as well as share ideas and process improvements for preventing recurrence.

II. Background

The goal of the Oil and Gas Industry Safety Data program is to provide BTS with essential information about accident precursors and other hazards associated with Outer Continental Shelf (OCS) oil and gas operations including but not limited to exploration and production (E&P.) This program collects voluntarily reported safety data.

A related goal of the ISD is to provide a mechanism whereby participating companies can submit safety data in whatever format they currently use to minimize incremental effort on the company's part. To realize the optimum benefits from an industrywide framework, all organizations associated with offshore E&P operations (operators, contractors, subcontractors, suppliers/OEMs) and/or regulatory agencies are encouraged to submit data voluntarily. BTS is conducting an Industry Safety Data (ISD) program pilot, in 2017–2018 with data from nine companies.

The value proposition of the ISD program is its focus on the continual improvement in safety performance, and its implementation of lessons learned from incidents and events that occur within the oil and gas industry. This is particularly important for major hazards and associated prevention/mitigation barriers. Several key aspects of this effort includes:

- Providing a solution for a central repository for collection, collaboration, and sharing of lessons learned from collected safety-related data,
- Identifying the type of data that will provide valuable information,
- Gaining alignment on incident and indicator definitions,
- Utilizing a secure process for collection and analysis of the data,
- Implementing a robust methodology for identifying systemic issues,
- Disseminating the results to stakeholders who can then take actions to reduce or eliminate the risk of recurrence through greater barrier integrity,
- Providing opportunities for stakeholders to network and benchmark performance, both individually and as an organization, and
- Establishing a framework wherein adverse actions cannot legally be taken against data submitters nor can raw data be used for regulatory development purposes.

One other related goal of the ISD program is to provide a mechanism whereby participating companies can submit safety data in whatever format they currently use to minimize incremental effort on the company's part.

One of the key benefits associated with submitting safety data directly to BTS for review and analysis, is that it addresses concerns related to protection of the data source. SafeOCS, including the ISD, operates under a Federal law, the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), which requires the program to protect the identity of the reporter and treat reports confidentially. Information submitted under CIPSEA is also protected from release to other government agencies, Freedom of Information Act (FOIA) requests, and subpoena. Even regulatory agencies, such as BSEE, cannot have access to the identity of those submitting reports under the program. In addition, the information from individual records cannot be used for enforcement purposes. CIPSEA is subject to strict criminal and civil penalties for noncompliance.

Once data is aggregated, BTS will analyze safety data reports submitted by companies involved in OCS activities. BTS will also work with subject matter experts to further analyze these reports to identify potential causal factors and trends. The results of these aggregated analyses will be distributed by BTS through public reports. Industry workshops may then be scheduled to allow operators, service companies, drilling contractors, regulators, and other stakeholders to discuss the results and share lessons learned.

This data collection will provide participating members within the oil and gas industry, a trusted means to report sensitive proprietary and safety information related to operations in the OCS, and to foster trust in the confidential collection, handling, and storage of the raw data. BTS will use the

data collected to establish a comprehensive source of the safety related data for statistical purposes. With input from subject matter experts, BTS will process and analyze information on Safety Data and associated metadata, and publish the results of such analyses in public reports. These reports will provide the industry, all OCS stakeholders and BSEE with essential information about critical safety issues for offshore operations and production.

The BTS Director or Deputy Director will review all analyses and reports, and issue approval for publication. While BTS's direct involvement will end after the aggregated trends report is published, the ISD program may form a committee to address the analytical findings.

III. Request for Public Comment

BTS requests comments on any aspects of this information collection request, including: (1) Ways to enhance the quality, usefulness, and clarity of the collected information; and (2) ways to minimize the collection burden without reducing the quality of the information collected, including additional use of automated collection techniques or other forms of information technology.

Patricia Hu,

Director, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation.

[FR Doc. 2018–09613 Filed 5–4–18; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1098–C

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 1098–C, Contributions of Motor Vehicles, Boats, and Airplanes.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sandra Lowery at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (202) 317–5754 or through the internet, at *Sandra.J.Lowery@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Contributions of Motor Vehicles, Boats, and Airplanes.

OMB Number: 1545–1959.

Form Number: Form 1098–C.

Abstract: Section 884 of the American Jobs Creation Act of 2004 (Pub. L. 108–357) added new paragraph 12 to section 170(f) for contributions of used motor vehicles, boats, and airplanes. Section 170(f)(12) requires that a donee organization provide an acknowledgement to the donor of this type of property and is required to file the same information to the Internal Revenue Service. 1098–C may be used as the acknowledgement and it, or an acceptable substitute, must be filed with the IRS.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Not for-profit organizations.

Estimated Number of Respondents: 151,000.

Estimated Time per Respondent: 18 minutes.

Estimated Total Annual Burden Hours: 46,810.00.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 23, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09596 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8693

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Low-Income Housing Credit Disposition Bond.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Low-Income Housing Credit Disposition Bond.

OMB Number: 1545–1029.

Form Number: 8693.

Abstract: Form 8693 is needed per IRC section 42(j)(6) to post bond or establish a Treasury Direct Account and waive the recapture requirements under section 42(j) for certain disposition of a building on which the low-income housing credit was claimed. Internal Revenue regulations section 301.7101–1 requires that the posting of a bond must be done on the appropriate form as determined by the Internal Revenue Service.

Current Actions: There are no changes being made to Form 8693 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 667.

Estimated Time Per Respondent: 5 hrs., 23 mins.

Estimated Total Annual Burden Hours: 3,589.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including 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.

Approved: April 26, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09598 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Special Valuation Rules.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sandra Lowery at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (202) 317–5754 or through the internet, at *Sandra.J.Lowery@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Special Valuation Rules.

OMB Number: 1545–1241.

Regulation Project Number: PS–92–90 [TD 8395].

Abstract: Section 2701 of the Internal Revenue Code allows various elections by family members who make gifts of common stock or partnership interests and retain senior interests in the same entity. This regulation provides guidance on how taxpayers make these elections, what information is required, and how the transfer is to be disclosed on the gift tax return (Form 709).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 1,200.

Estimated Time Per Respondent: 25 minutes.

Estimated Total Annual Burden Hours: 496.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 23, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09595 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Guidance on Passive Foreign Investment Company (PFIC) Purging Elections.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Guidance on Passive Foreign Investment Company (PFIC) Purging Elections.

OMB Number: 1545–1965.

Regulation Project Number: TD 9360.

Abstract: The IRS needs the information to substantiate the taxpayer's computation of the taxpayer's share of the PFIC's post-1986 earning and profits.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 250.

Estimated Time Per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 250.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including 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.

Approved: April 30, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09594 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Rev. Proc. 99–17

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Mark to Market Election for Commodities Dealers and Securities and Commodities Traders.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this revenue procedure should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Mark to Market Election for Commodities Dealers and Securities and Commodities Traders.

OMB Number: 1545–1641.

Revenue Procedure Number: Rev. Proc. 99–17 (Revenue Procedure 99–17 is modified by Revenue Procedure 99–49).

Abstract: The revenue procedure prescribes the time and manner for dealers in commodities and traders in securities or commodities to elect to use the mark-to-market method of accounting under Sec. 475(e) or (f) of the Internal Revenue Code. The collections of information of this revenue procedure are required by the IRS in order to facilitate monitoring taxpayers changing accounting methods resulting from making the elections under Sec. 475(e) or (f).

Current Actions: There are no changes being made to this Rev. Proc. at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 30 mins.

Estimated Total Annual Burden Hours: 500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including 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.

Approved: April 26, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09592 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Regulations Under Section 382 of the Internal Revenue Code of 1986; Application of Section 382 in Short Taxable Years and With Respect to Controlled Groups.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Regulations Under Section 382 of the Internal Revenue Code of 1986; Application of Section 382 in Short Taxable Years and With Respect to Controlled Groups.

OMB Number: 1545–1434.

Regulation Project Number: TD 8825.

Abstract: Section 382 limits the amount of income that can be offset by loss carryovers after an ownership change. These regulations provide rules for applying section 382 in the case of short taxable years and with respect to controlled groups.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,500.

Estimated Time Per Respondent: 15 mins.

Estimated Total Annual Burden Hours: 875.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including 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.

Approved: April 30, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09593 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–S

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Proceeds From Real Estate Transactions.

DATES: Written comments should be received on or before July 6, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Proceeds From Real Estate Transactions.

OMB Number: 1545–0997.

Form Number: 1099–S.

Abstract: Internal Revenue Code section 6045(e) and the regulations there under require persons treated as real estate brokers to submit an information return to the IRS to report the gross proceeds from real estate transactions. Form 1099–S is used for this purpose. The IRS uses the information on the form to verify compliance with the reporting rules regarding real estate transactions.

Current Actions: There are no changes being made to Form 1099–S at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals or households.

Estimated Number of Respondents: 2,573,400.

Estimated Time Per Respondent: 10 mins.

Estimated Total Annual Burden Hours: 411,744.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the

agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including 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.

Approved: April 26, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–09597 Filed 5–4–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Request for Applications for Appointment to the Citizens Coinage Advisory Committee

AGENCY: United States Mint, Treasury.

ACTION: Request for applications for appointment to the Citizens Coinage Advisory Committee.

SUMMARY: Pursuant to United States Code, the United States Mint is accepting applications for appointment to the Citizens Coinage Advisory Committee (CCAC) as a member representing the *interests of the general public* in the coinage of the United States.

FOR FURTHER INFORMATION CONTACT: Betty Birdsong, Acting United States Mint Liaison to the CCAC; 801 9th Street NW; Washington, DC 20220, or call 202–354–7770.

SUPPLEMENTARY INFORMATION:

The CCAC was established to:

- Advise the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals produced by the United States Mint.
- Advise the Secretary of the Treasury with regard to the events, persons, or places that the CCAC recommends to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Make recommendations with respect to the mintage level for any commemorative coin recommended.

Total membership consists of eleven voting members appointed by the Secretary of the Treasury:

- One person specially qualified by virtue of his or her education, training, or experience as nationally or internationally recognized curator in the United States of a numismatic collection;
- One person specially qualified by virtue of his or her experience in the medallic arts or sculpture;
- One person specially qualified by virtue of his or her education, training, or experience in American history;
- One person specially qualified by virtue of his or her education, training, or experience in numismatics;
- Three persons who can represent the interests of the general public in the coinage of the United States; and
- Four persons appointed by the Secretary of the Treasury on the basis of the recommendations by the House and Senate leadership.

Members are appointed for a term of four years. No individual may be appointed to the CCAC while serving as an officer or employee of the Federal Government.

The CCAC is subject to the direction of the Secretary of the Treasury. Meetings of the CCAC are open to the public and are held approximately four to six times per year. The United States Mint is responsible for providing the necessary support, technical services, and advice to the CCAC. CCAC members are not paid for their time or services, but, consistent with Federal Travel Regulations, members are reimbursed for their travel and lodging expenses to attend meetings. Members are Special Government Employees and are subject to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2653).

The United States Mint will review all submissions and will forward its recommendations to the Secretary of the Treasury for appointment consideration. Candidates should include specific skills, abilities, talents, and credentials to support their applications. The United States Mint is interested in candidates who are recognized as having unique and valued talents or as an accomplished professional; have demonstrated experience, knowledge, interest, or background in a variety of fields, including numismatics, art, education, working with youth, or American heritage and culture; have demonstrated interest and a commitment to actively participate in meetings and activities, and a demonstrated understanding of the role of the CCAC and the obligations of a Special Government Employee; possess demonstrated leadership skills in their fields of expertise or discipline; possess a demonstrated desire for public service and have a history of honorable professional and personal conduct, as well as successful standing in their communities; and who are free of professional, political, or financial interests that could negatively affect their ability to provide impartial advice.

Application Deadline: Friday, May 18, 2018.

Receipt of Applications: Any member of the public wishing to be considered for participation on the CCAC should submit a resume and cover letter describing his or her reasons for seeking and qualifications for membership, by email to *info@ccac.gov* or by mail to the United States Mint; 801 9th Street NW; Washington, DC 20220; Attn: Greg Weinman. Submissions must be postmarked no later than Friday, May 18, 2018.

Notice Concerning Delivery of First-Class and Priority Mail: First-class mail to the United States Mint is put through an irradiation process to protect against biological contamination. Support materials put through this process may suffer irreversible damage. We encourage you to consider using alternate delivery services, especially when sending time-sensitive material.

Dated: May 1, 2018.

David J. Ryder,

Director, United States Mint.

[FR Doc. 2018–09628 Filed 5–4–18; 8:45 am]

BILLING CODE P

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of submission to Congress of amendments to the sentencing guidelines effective November 1, 2018.

SUMMARY: Pursuant to its authority, the Commission has promulgated amendments to the sentencing guidelines, policy statements, commentary, and statutory index. This notice sets forth the amendments and the reason for each amendment.

DATES: The Commission has specified an effective date of November 1, 2018, for the amendments set forth in this notice.

FOR FURTHER INFORMATION CONTACT: Christine Leonard, Director, Office of

Legislative and Public Affairs, (202) 502–4500, *pubaffairs@ussc.gov.*

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal courts pursuant to 28 U.S.C. 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. 994(o) and generally submits guideline amendments to the Congress pursuant to 28 U.S.C. 994(p) not later than the first day of May each year. Absent action of the Congress to the contrary, submitted amendments become effective by operation of law on the date specified by the Commission (generally November 1 of the year in which the amendments are submitted to Congress).

Notices of the proposed amendments were published in the **Federal Register** on August 25, 2017 (*see* 82 FR 40651) and January 26, 2018 (*see* 83 FR 3869). The Commission held public hearings on the proposed amendments in Washington, DC, on February 8 and March 14, 2018. On April 30, 2018, the Commission submitted these amendments to the Congress and specified an effective date of November 1, 2018.

The text of the amendments to the sentencing guidelines, policy statements, commentary, and statutory index, and the reason for each amendment, are set forth below. Additional information pertaining to the amendments described in this notice may be accessed through the Commission's website at *www.ussc.gov*.

Authority: 28 U.S.C. 994(a), (o), and (p); USSC Rules of Practice and Procedure 2.2, 4.1.

William H. Pryor Jr.,

Acting Chair.

Amendments to the Sentencing Guidelines, Policy Statements, and Official Commentary

1. *Amendment:* The Commentary to § 1B1.1 captioned ''Application Notes'' is amended in Note 1 by redesignating paragraphs (D) through (L) as paragraphs (E) through (M), respectively; and by inserting the following new paragraph (D):

''(D) 'Court protection order' means 'protection order' as defined by 18 U.S.C. 2266(5) and consistent with 18 U.S.C. 2265(b).''.

The Commentary to § 2B3.1 captioned ''Application Notes'' is amended in Note 2 by striking ''Application Note 1(D)(ii) of § 1B1.1'' and inserting ''Application Note 1(E)(ii) of § 1B1.1''.

The Commentary to § 2L1.1 captioned ''Application Notes'' is amended in Note 4 by striking ''Application Note 1(L) of § 1B1.1'' and inserting ''Application Note 1(M) of § 1B1.1''.

Section 4A1.3(a)(2) is amended by striking ''subsection (a)'' and inserting ''subsection (a)(1)''; and by striking ''sentences for foreign and tribal offenses'' and inserting ''sentences for foreign and tribal convictions''.

The Commentary to § 4A1.3 captioned ''Application Notes'' is amended—

in Note 2 by inserting at the end the following new paragraph (C):

''(C) *Upward Departures Based on Tribal Court Convictions.*—In determining whether, or to what extent, an upward departure based on a tribal court conviction is appropriate, the court shall consider the factors set forth in § 4A1.3(a) above and, in addition, may consider relevant factors such as the following:

(i) The defendant was represented by a lawyer, had the right to a trial by jury, and received other due process protections consistent with those provided to criminal defendants under the United States Constitution.

(ii) The defendant received the due process protections required for criminal defendants under the Indian Civil Rights Act of 1968, Public Law 90–284, as amended.

(iii) The tribe was exercising expanded jurisdiction under the Tribal Law and Order Act of 2010, Public Law 111–211.

(iv) The tribe was exercising expanded jurisdiction under the Violence Against Women Reauthorization Act of 2013, Public Law 113–4.

(v) The tribal court conviction is not based on the same conduct that formed the basis for a conviction from another jurisdiction that receives criminal history points pursuant to this Chapter.

(vi) The tribal court conviction is for an offense that otherwise would be counted under § 4A1.2 (Definitions and Instructions for Computing Criminal History).'';

and in Note 3 by striking ''A departure below the lower limit of the applicable guideline range for Criminal History Category I is prohibited under subsection (b)(2)(B)'' and inserting ''A departure below the lower limit of the applicable guideline range for Criminal History Category I is prohibited under subsection (b)(2)(A)''.

Reason for Amendment: This two-part amendment addresses federal sentencing issues related to offenses committed in Indian country. The amendment responds to the findings and recommendations made by the Commission's *ad hoc* Tribal Issues Advisory Group in its report to the Commission. *See Report of the Tribal Issues Advisory Group* (May 16, 2016), *http://www.ussc.gov/research/research-publications/report-tribal-issues-advisory-group.*

The amendment adds a definition of ''court protection order'' in the guidelines. This issue was initially raised by the Commission's Victims Advisory Group and subsequently addressed in the Tribal Issues Advisory Group's May 2016 report. The amendment amends § 1B1.1 (Application Instructions) to add a definition of ''court protection order'' that incorporates by reference the statutory definition of a ''protection order'' as set forth in 18 U.S.C. 2266(5) and consistent with 18 U.S.C. 2265(b). Under the *Guidelines Manual,* the violation of a court protection order is a specific offense characteristic in three Chapter Two offense guidelines. *See* USSG §§ 2A2.2 (Aggravated Assault), 2A6.1 (Threatening or Harassing Communications; Hoaxes; False Liens), and 2A6.2 (Stalking or Domestic Violence).

The amendment responds to concerns that the term ''court protection order'' has not been defined in the guidelines and should be clarified. Providing a clear definition of a ''court protection order'' in the *Guidelines Manual* will ensure that orders used for sentencing enhancements are the result of court proceedings assuring appropriate due process protections, that there is a consistent identification and treatment of such orders, and that such orders issued by tribal courts receive treatment consistent with that of other issuing jurisdictions. The amendment also makes conforming technical changes to the Commentary of §§ 2B1.3 (Robbery) and 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien).

The amendment addresses the treatment of tribal court convictions in Chapter Four (Criminal History and Criminal Livelihood) of the *Guidelines Manual.* Subsection (i) of § 4A1.2 (Definitions and Instructions for Computing Criminal History) provides that sentences resulting from tribal court convictions are not counted in calculating a defendant's criminal history score but may be considered for an upward departure under § 4A1.3 (Departures Based on Inadequacy of Criminal History Category (Policy Statement)). Section 4A1.3 provides for an upward departure for prior sentences that are not used in computing the

criminal history category, such as sentences for tribal convictions, where reliable information suggests that the defendant's criminal history category under-represents the seriousness of the defendant's prior record.

Tribal court convictions have been excluded from the criminal history score but have been a legitimate basis for upward departure since the original guidelines were promulgated in 1987. In recent years, some tribal courts have gained enhanced sentencing authority under the Tribal Law and Order Act of 2010, Public Law 111–211 (July 29, 2010), and expanded jurisdiction over non-Indian defendants in domestic abuse cases under the Violence Against Women Act Reauthorization Act of 2013, Public Law 113–4 (Mar. 7, 2013). Many tribal courts have also begun to increase due process protections and reliable record-keeping.

In recognition of these developments, the amendment provides additional guidance to courts on how to apply the departure provision at § 4A1.3 in cases involving a defendant with a history of tribal convictions. Specifically, the amendment amends the Commentary to § 4A1.3 at Application Note 2(c) to provide the following non-exhaustive list of six factors that courts may consider in deciding whether or to what extent an upward departure based on a tribal conviction may be appropriate:

(i) The defendant was represented by a lawyer, had the right to a trial by jury, and received other due process protections consistent with those provided to criminal defendants under the United States Constitution.

(ii) The defendant received the due process protections required for criminal defendants under the Indian Civil Rights Act of 1968, Public Law 90–284, as amended.

(iii) The tribe was exercising expanded jurisdiction under the Tribal Law and Order Act of 2010, Public Law 111–211.

(iv) The tribe was exercising expanded jurisdiction under the Violence Against Women Reauthorization Act of 2013, Public Law 113–4.

(v) The tribal court conviction is not based on the same conduct that formed the basis for a conviction from another jurisdiction that receives criminal history points pursuant to this Chapter.

(vi) The tribal court conviction is for an offense that otherwise would be counted under § 4A1.2 (Definitions and Instructions for Computing Criminal History).

Because of the many cultural and historical differences among federally-recognized tribes, and especially among their tribal court systems, the Commission determined that—despite recent developments in Indian law to enlarge the scope of tribal court jurisdiction and the availability of due process in tribal court proceedings—a single approach to the consideration of tribal convictions would be difficult and could potentially lead to a disparate result among Indian defendants in federal courts. The amendment, therefore, reflects the Commission's view that additional guidance about how to apply the departure provision at § 4A1.3 in cases involving a defendant with a history of tribal convictions is appropriate, and that the non-exhaustive list of factors provides appropriate guidance and a more structured analytical framework under § 4A1.3. The Commission intends, as informed by the Tribal Issues Advisory Group Report and public comment, that none of the factors should be determinative, but collectively the factors reflect important considerations to help courts balance the rights of defendants, the unique and important status of tribal courts, the need to avoid disparate sentences because of varying tribal court practices and circumstances, and the goal of accurately assessing a defendant's criminal history.

The amendment also includes two technical changes to § 4A1.3. First, the amendment amends § 4A1.3(a)(2)(A) to change the phrase ''sentences for foreign and tribal offenses'' to ''sentences for foreign and tribal convictions'' to track the parallel language in § 4A1.2(h) and (i). Second, the amendment makes a clerical change in Application Note 3 to correct an inaccurate reference to § 4A1.3(b)(2)(B).

2. *Amendment:* Section 2B1.1(b) is amended by redesignating paragraphs (13) through (19) as paragraphs (14) through (20), respectively; and by inserting the following new paragraph (13):

''(13) If the defendant was convicted under 42 U.S.C. 408(a), 1011(a), or 1383a(a) and the statutory maximum term of ten years' imprisonment applies, increase by 4 levels. If the resulting offense level is less than 12, increase to level 12.'';

and in paragraph (17) (as so redesignated) by striking ''subsections (b)(2) and (b)(16)(B)'' and inserting ''subsections (b)(2) and (b)(17)(B)''.

The Commentary to § 2B1.1 captioned ''Application Notes'' is amended—

by redesignating Notes 11 through 20 as Notes 12 through 21, respectively; and by inserting the following new Note 11:

''11. *Interaction of Subsection (b)(13) and § 3B1.3 (Abuse of Position of Trust or Use of Special Skill).*—If subsection (b)(13) applies, do not apply § 3B1.3.'';

in Note 12 (as so redesignated) by striking ''(b)(14)'' both places such term appears and inserting ''(b)(15)'';

in Note 13 (as so redesignated) by striking ''(b)(16)(A)'' both places such term appears and inserting ''(b)(17)(A)'';

in Note 14 (as so redesignated) by striking ''(b)(16)(B)'' and inserting ''(b)(17)(B)''; by striking ''(b)(16)(B)(i)'' and inserting ''(b)(17)(B)(i)''; and by striking ''(b)(16)(B)(ii)'' and inserting ''(b)(17)(B)(ii)'';

in Note 15 (as so redesignated) by striking ''(b)(18)'' both places such term appears and inserting ''(b)(19)''; by striking ''(b)(18)(A)(iii)'' both places such term appears and inserting ''(b)(19)(A)(iii)''; and by striking ''(b)(16)(B)'' both places such term appears and inserting ''(b)(17)(B)'';

in Note 16 (as so redesignated) by striking ''(b)(19)'' each place such term appears and inserting ''(b)(20)'';

and in Note 21(B) (as so redesignated) by striking ''(b)(18)(A)(iii)'' and inserting ''(b)(19)(A)(iii)''.

The Commentary to § 2B1.1 captioned ''Background'' is amended by striking ''(b)(13)'' and inserting ''(b)(14)''; by striking ''(b)(15)(B)'' and inserting ''(b)(16)(B)''; by striking ''(b)(16)(A)'' and inserting ''(b)(17)(A)''; by striking ''(b)(16)(B)(i)'' and inserting ''(b)(17)(B)(i)''; by striking ''Subsection (b)(17) implements the directive in section 209'' and inserting ''Subsection (b)(18) implements the directive in section 209''; by striking ''Subsection (b)(18) implements the directive in section 225(b)'' and inserting ''Subsection (b)(19) implements the directive in section 225(b)''; and by striking ''(b)(18)(B)'' and inserting ''(b)(19)(B)''.

Appendix A (Statutory Index) is amended in the line referenced to 42 U.S.C. 408 by inserting '', 2X1.1'' at the end; in the line referenced to 42 U.S.C. 1011 by inserting '', 2X1.1'' at the end; and in the line referenced to 42 U.S.C. 1383a(a) by inserting '', 2X1.1'' at the end.

Reason for Amendment: This amendment responds to the Bipartisan Budget Act of 2015 (''the Act''), Public Law 114–74 (Nov. 2, 2015), which made numerous changes to the statutes governing Social Security fraud offenses at 42 U.S.C. 408, 1011, and 1383a. The Act added new subsections criminalizing conspiracy to commit fraud for selected substantive offenses already proscribed in Title 42 and added an increased statutory penalty provision for certain persons who

commit fraud offenses under the relevant Social Security programs.

In response to these statutory changes, the amendment makes changes to both § 2B1.1 (Theft, Property Destruction, and Fraud) and Appendix A (Statutory Index). The amendment to § 2B1.1 addresses the increased penalty provisions of the Act by adding a new specific offense characteristic with a 4-level enhancement and a minimum offense level of 12 for those defendants subject to a 10-year statutory maximum, and adds commentary precluding the application of an adjustment under § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) when the new enhancement applies. The amendment to Appendix A references the new conspiracy subsections to the appropriate guidelines.

First, the amendment adds a specific offense characteristic to § 2B1.1 in response to the enhanced penalty provisions of the Act. The new enhancement provides for a 4-level increase, as well as a minimum offense level of 12, for those defendants convicted under the relevant statutes and subject to the 10-year statutory maximum. The enhancement reflects both Congress's and the Commission's determination regarding the seriousness of these offenses, and further reflects the difficulty in calculating the true harm caused by such defendants, including the harm to the integrity and financial strength of the Social Security program and to legitimate Social Security program benefit recipients who face delays as a result of the review of claims submitted in these cases. The Commission was also persuaded in its determination by the significant administrative efforts and costs resulting from the regulatory requirement that the Social Security Administration review and redetermine the benefit eligibility for every benefit recipient associated with the defendant, whether part of the fraudulent conduct or not. The new enhancement reflects the increased harm caused by these types of cases compared to those types of fraud sentenced under § 2B1.1 for which the loss table more appropriately reflects the severity of the offense.

Similar to other minimum offense levels in § 2B1.1, the minimum offense level is intended to account for the difficulty in calculating the amount of loss, as well as the unique and non-monetary harms associated with offenses sentenced under the Act. As previously explained in similar contexts, ''[t]he Commission frequently adopts a minimum offense level in circumstances in which, as in these cases, loss as calculated by the guidelines is difficult to compute or does not adequately account for the harm caused by the offense.'' USSG, App. C, Amendment 719 (effective Nov. 1, 2008).

In establishing the 4-level increase, the Commission also added commentary precluding the application of an adjustment under § 3B1.3 to those defendants who are subject to the Act's increased statutory maximum penalty. In the Act, Congress specifically defined positions of trust in the context of Social Security fraud by subjecting to the increased statutory maximum penalties those defendants who were:

a person who receives a fee or other income for services performed in connection with any determination with respect to benefits under this subchapter (including a claimant representative, translator, or current or former employee of the Social Security Administration), or who is a physician or other health care provider who submits, or causes the submission of, medical or other evidence in connection with any such determination. . . .

The Commission precluded application of § 3B1.3 to these defendants because the new 4-level enhancement fully accounts for their special position. Addressing the abuse of special position in this manner will avoid uncertainty, prolonged sentencing hearings, and appeals regarding application of the abuse of trust adjustment to offenders subject to the increased statutory maximum penalties of the Act.

Second, the amendment amends Appendix A to reference the new conspiracy offenses under 42 U.S.C. 408, 1011, and 1383a to § 2X1.1 (Attempt, Solicitation, or Conspiracy (Not Covered by a Specific Offense Guideline)). The Commission determined that referencing these conspiracy provisions to § 2X1.1, as well as the guideline referenced in the statutory index for the substantive offense, is consistent with the instructions at § 1B1.2 (Applicable Guidelines).

3. *Amendment:* Section 2D1.1 is amended—

by redesignating subsections (b)(13) through (b)(17) as subsections (b)(14) through (b)(18), respectively; and by inserting the following new subsection (b)(13):

''(13) If the defendant knowingly misrepresented or knowingly marketed as another substance a mixture or substance containing fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) or a fentanyl analogue, increase by 4 levels.'';

and in each of subsections (c)(1) through (c)(14) by striking ''of Fentanyl'' each place such term appears and inserting ''of Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide)''.

The annotation to § 2D1.1(c) captioned ''Notes to Drug Quantity Table'' is amended by inserting at the end the following new Note (J):

''(J) Fentanyl analogue, for the purposes of this guideline, means any substance (including any salt, isomer, or salt of isomer thereof), whether a controlled substance or not, that has a chemical structure that is similar to fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide).''.

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended—

in Note 6 by striking ''Any reference to a particular controlled substance in these guidelines includes all salts, isomers, all salts of isomers, and, except as otherwise provided, any analogue of that controlled substance'' and inserting ''Except as otherwise provided, any reference to a particular controlled substance in these guidelines includes all salts, isomers, all salts of isomers, and any analogue of that controlled substance''; and by striking ''For purposes of this guideline 'analogue' has the meaning'' and inserting ''Unless otherwise specified, 'analogue,' for purposes of this guideline, has the meaning'';

in Note 8(D)—

in the table under the heading ''Schedule I or II Opiates*''—

by striking the following two lines:

''1 gm of Alpha-Methylfentanyl = 10 kg of marihuana''

''1 gm of 3-Methylfentanyl = 10 kg of marihuana'';

and by inserting after the line referenced to Fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] Propanamide) the following line:

''1 gm of a Fentanyl Analogue = 10 kg of marihuana'';

in the table under the heading ''Cocaine and Other Schedule I and II Stimulants (and their immediate precursors)*'', by striking the following line:

''1 gm of Methcathinone = 380 gm of marihuana'';

by inserting after the table under the heading ''Cocaine and Other Schedule I and II Stimulants (and their immediate precursors)*'' the following new table:

''*Synthetic Cathinones (except Schedule III, IV, and V Substances)**

1 gm of a synthetic cathinone (except a Schedule III, IV, or V substance) = 380 gm of marihuana

Provided, that the minimum offense level from the Drug Quantity Table for any synthetic cathinone (except a Schedule III, IV, or V substance) individually, or in combination with another controlled substance, is level 12.'';

by inserting after the table under the heading ''Schedule I Marihuana'' the following new table:

''*Synthetic Cannabinoids (except Schedule III, IV, and V Substances)**

1 gm of a synthetic cannabinoid (except a Schedule III, IV, or V substance) = 167 gm of marihuana

Provided, that the minimum offense level from the Drug Quantity Table for any synthetic cannabinoid (except a Schedule III, IV, or V substance) individually, or in combination with another controlled substance, is level 12.

'Synthetic cannabinoid,' for purposes of this guideline, means any synthetic substance (other than synthetic tetrahydrocannabinol) that binds to and activates type 1 cannabinoid receptors (CB_1 receptors).'';

in Note 16 by striking ''§ 2D1.1(b)(15)(D)'' and inserting ''§ 2D1.1(b)(16)(D)'';

in Note 18 by striking ''(b)(13)'' and inserting ''(b)(14)''; by striking ''(b)(13)(A)'' each place such term appears and inserting ''(b)(14)(A)''; by striking ''(b)(13)(C)–(D)'' and inserting ''(b)(14)(C)–(D)''; by striking ''(b)(13)(C)(ii)'' and inserting ''(b)(14)(C)(ii)''; and by striking ''(b)(13)(D)'' and inserting ''(b)(14)(D)''.

in Note 19 by striking ''(b)(14)'' each place such term appears and inserting ''(b)(15)''; and by striking ''(b)(13)(A)'' and inserting ''(b)(14)(A)'';

in Note 20 by striking ''(b)(15)'' and inserting ''(b)(16)''; by striking ''(b)(15)(B)'' both places such term appears and inserting ''(b)(16)(B)''; by striking ''(b)(15)(C)'' each place such term appears and inserting ''(b)(16)(C)''; and by striking ''(b)(15)(E)'' both places such term appears and inserting ''(b)(16)(E)'';

in Note 21 by striking ''(b)(17)'' each place such term appears and inserting ''(b)(18)'';

and in Note 27 by inserting at the end the following new paragraphs:

''(D) *Departure Based on Potency of Synthetic Cathinones.*—In addition to providing marihuana equivalencies for specific controlled substances and groups of substances, the Drug Equivalency Tables provide marihuana equivalencies for certain classes of controlled substances, such as synthetic cathinones. In the case of a synthetic cathinone that is not specifically referenced in this guideline, the marihuana equivalency for the class should be used to determine the appropriate offense level. However, there may be cases in which a substantially lesser or greater quantity of a synthetic cathinone is needed to produce an effect on the central nervous system similar to the effect produced by a typical synthetic cathinone in the class, such as methcathinone or alpha-PVP. In such a case, a departure may be warranted. For example, an upward departure may be warranted in cases involving MDPV, a substance of which a lesser quantity is usually needed to produce an effect on the central nervous system similar to the effect produced by a typical synthetic cathinone. In contrast, a downward departure may be warranted in cases involving methylone, a substance of which a greater quantity is usually needed to produce an effect on the central nervous system similar to the effect produced by a typical synthetic cathinone.

(E) *Departures for Certain Cases involving Synthetic Cannabinoids.*—

(i) *Departure Based on Concentration of Synthetic Cannabinoids.*—Synthetic cannabinoids are manufactured as powder or crystalline substances. The concentrated substance is then usually sprayed on or soaked into a plant or other base material, and trafficked as part of a mixture. Nonetheless, there may be cases in which the substance involved in the offense is a synthetic cannabinoid not combined with any other substance. In such a case, an upward departure would be warranted.

There also may be cases in which the substance involved in the offense is a mixture containing a synthetic cannabinoid diluted with an unusually high quantity of base material. In such a case, a downward departure may be warranted.

(ii) *Downward Departure Based on Potency of Synthetic Cannabinoids.*—In the case of a synthetic cannabinoid that is not specifically referenced in this guideline, the marihuana equivalency for the class should be used to determine the appropriate offense level. However, there may be cases in which a substantially greater quantity of a synthetic cannabinoid is needed to produce an effect on the central nervous system similar to the effect produced by a typical synthetic cannabinoid in the class, such as JWH–018 or AM–2201. In such a case, a downward departure may be warranted.''.

The Commentary to § 2D1.1 captioned ''Background'' is amended by striking ''(b)(13)(A)'' and inserting ''(b)(14)(A)''; by striking ''(b)(13)(C)(ii)'' and inserting ''(b)(14)(C)(ii)''; by striking ''Subsection (b)(15) implements the directive to the Commission in section 6(3)'' and inserting ''Subsection (b)(16) implements the directive to the Commission in section 6(3)''; and by striking ''Subsection (b)(16) implements the directive to the Commission in section 7(2)'' and inserting ''Subsection (b)(17) implements the directive to the Commission in section 7(2)''.

The Commentary to § 2D1.6 captioned ''Application Note'' is amended in Note 1 by striking '', fentanyl'' and inserting '', fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide)''.

Section 2D1.14(a)(1) is amended by striking ''(b)(17)'' and inserting ''(b)(18)''.

The Commentary to § 3B1.4 captioned ''Application Notes'' is amended in Note 2 by striking ''§ 2D1.1(b)(15)(B)'' and inserting ''§ 2D1.1(b)(16)(B)''.

The Commentary to § 3C1.1 captioned ''Application Notes'' is amended in Note 7 by striking ''§ 2D1.1(b)(15)(D)'' and inserting ''§ 2D1.1(b)(16)(D)''.

Reason for Amendment: This amendment is a result of the Commission's multi-year study of offenses involving synthetic cathinones (such as methylone, MDPV, and mephedrone) and synthetic cannabinoids (such as JWH–018 and AM–2201), as well as tetrahydrocannabinol (THC), fentanyl, and fentanyl analogues. The study included extensive data collection, review of scientific literature, multiple public comment periods, and four public hearings. The resulting amendment makes various changes to § 2D1.1 pertaining to synthetic controlled substances.

The amendment first addresses fentanyl and fentanyl analogues. The Commission learned that while fentanyl has long been a drug of abuse, there are several indications that its abuse has become both more prevalent and more dangerous in recent years. For example, the Drug Enforcement Administration observed a dramatic increase in fentanyl reports between 2013 and 2015, and the Centers for Disease Control and Prevention reported that there were 9,580 deaths involving synthetic opioids (a category including fentanyl) in 2015, a 72.2 percent increase from 2014. The Commission received testimony and other information indicating that fentanyl and its analogues are often trafficked mixed with other controlled substances, including heroin and cocaine. In other instances, fentanyl is placed in pill or tablet form by drug traffickers. Although some purchasers of these substances may be aware that they

contain fentanyl (or even seek them out for that reason), others may believe that they are purchasing heroin or pharmaceutically manufactured opioid pain relievers.

Because of fentanyl's extreme potency, the risk of overdose death is great, particularly when the user is inexperienced or unaware of what substance he or she is using. To address this harm, the amendment adds a new specific offense characteristic at § 2D1.1(b)(13) to provide for a 4-level increase whenever the defendant knowingly misrepresented or knowingly marketed as another substance a mixture or substance containing fentanyl or a fentanyl analogue. The Commission determined that it is appropriate for traffickers who knowingly misrepresent fentanyl or a fentanyl analogue as another substance to receive additional punishment. If an offender does not know the substance contains fentanyl or a fentanyl analogue, the enhancement does not apply. The specific offense characteristic includes a *mens rea* requirement to ensure that only the most culpable offenders are subjected to these increased penalties.

The amendment also makes a definitional change in the *Guidelines Manual.* Title 21, United States Code, refers to fentanyl by reference to its chemical name (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide) and sets mandatory minimum penalties for certain quantities of this substance and for analogues of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide, although lesser quantities of the analogues are required to trigger the mandatory minimum penalties. *See, e.g.,* 21 U.S.C. 841(b)(1)(A)(vi). Consistent with its past practice concerning setting drug-trafficking penalties, the Commission relied upon the statutory framework in setting penalties for fentanyl and fentanyl analogues. Fentanyl has a marihuana equivalency of 1:2,500, while fentanyl analogues have a marihuana equivalency of 1:10,000. In the *Guidelines Manual,* however, the Commission did not use the chemical name for fentanyl reflected in Title 21. Instead, the Commission used the terms ''fentanyl'' and ''fentanyl analogue'' in the Drug Quantity Table.

Commission data suggests that offenses involving fentanyl analogues are increasing in the federal caseload. In studying these cases, the Commission has learned that the reference to ''fentanyl analogue'' in the Drug Quantity Table may interact in an unintended way with the definition of ''analogue'' provided by Application Note 6 and Section 802(32) of Title 21, United States Code. Because the guideline incorporates by reference the statutory definition of ''controlled substance analogue,'' and that definition specifically excludes already listed ''controlled substances,'' it appears that a scheduled fentanyl analogue cannot constitute a ''controlled substance analogue,'' and thus does not constitute a fentanyl ''analogue'' for purposes of § 2D1.1. This may have the result that, at sentencing, fentanyl analogues that have already been scheduled must go through the Application Note 6 process to determine the substance most closely related to them.

Additionally, based on implementation of Application Note 6, many courts have then sentenced such analogue cases at the lower fentanyl ratio rather than the higher ratio applicable to fentanyl analogues in the Drug Quantity Table. To address this problem, the amendment adopts a new definition of ''fentanyl analogue'' as ''any substance (including any salt, isomer, or salt of isomer), whether a controlled substance or not, that has a chemical structure that is similar to fentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide).'' This portion of the amendment also amends the Drug Quantity Table to clarify that § 2D1.1 uses the term ''fentanyl'' to refer to the chemical name identified by statute and deletes the current listings for alpha-methylfentanyl and 3-methylfentanyl from the Drug Equivalency Tables.

The Commission determined that adopting this definition of ''fentanyl analogue'' will create a class of fentanyl analogues identical to that already created by statute, clarify the legal confusion that has resulted from the current definition of ''analogue'' in § 2D1.1, and reaffirm that fentanyl analogues are treated differently than fentanyl under the guidelines as well as the statute. Striking the separate references to alpha-methylfentanyl and 3-methylfentanyl will result in the treatment of these substances in common with all other fentanyl analogues. This change, in combination with the adoption of the definition of ''fentanyl analogue'' and addition of fentanyl analogue to the Drug Equivalency Tables, will limit the use of the listing for ''fentanyl'' to those cases involving the specific substance named in Title 21.

Next, the amendment addresses synthetic cathinones and synthetic cannabinoids. The Commission received comment from the Department of Justice and others expressing concern that the guidelines do not contain specific ''marihuana equivalencies'' for synthetic cathinones, such as methylone, mephedrone, and MDPV, or synthetic cannabinoids, such as JWH–018 and AM–2201. For substances that do not appear in either the Drug Quantity Table or the Drug Equivalency Table, Application Note 6 provides courts the process for calculating drug quantities. The note directs courts to identify the ''most closely related controlled substance referenced in [§ 2D1.1]'' and to then use that drug's ratio to marihuana to calculate the quantity for purposes of determining the base offense level. Commenters advised that this process is a time-consuming, burdensome task that leads to sentencing disparities. Because Commission data indicated that the majority of cases relying on the Application Note 6 process involved synthetic cathinones and synthetic cannabinoids, the Commission concluded that this amendment will alleviate the burden associated with its application.

Synthetic cathinones, also known as ''bath salts,'' are human-made substances chemically related to cathinone, a stimulant found in the khat plant. Although the Commission's study originally focused on specified cathinones, such as methylone, MDPV, and mephedrone, the Commission received comments indicating that new substances are regularly developed and trafficked and that it would not be feasible to establish a new ratio as each new substance enters the market. Given the large number of potential substances, the Commission found it impracticable to add individual marihuana equivalencies for every synthetic cathinone. In contrast, the Commission determined a class-based approach for synthetic cathinones should capture both current and future synthetic cathinones.

The Commission has determined that synthetic cathinones constitute a well-defined class. Specifically, testimony and comment presented to the Commission consistently indicated that the whether a substance is a synthetic cathinone is not subject to debate. Likewise, comments and testimony made clear that synthetic cathinones share stimulant characteristics and hallucinogenic effects. The Commission determined that a precise definition is not necessary for such substances and that a class-based structure could be reasonably adopted. The Commission likewise determined that, because the class would encompass methcathinone, currently the lone specifically listed synthetic cathinone, the separate reference to methcathinone in the Drug

Equivalency Table should be deleted. Given the Commission's priority to alleviate the burdens associated with the Application Note 6 process and the impracticality of adding many new marihuana equivalencies, the Commission concluded the class-based approach strikes a middle ground between precision and ease of guideline application.

The amendment creates an entry in the Drug Equivalency Tables for the class of synthetic cathinones, providing a marihuana equivalency of 1 gram of a synthetic cathinone (except a Schedule III, IV, or V substance) equals 380 grams of marihuana and applies a minimum base offense level of 12 to the class of synthetic cathinones. The Commission set a minimum base offense level of 12 for the class of synthetic cathinones to maintain consistency with the treatment of other controlled substances. With limited exceptions, all other Schedule I and II controlled substances are subject to the same minimum base offense level. The Commission was not presented with testimony or commentary that indicated a compelling basis to except synthetic cathinones from the minimum offense level.

The Commission adopted the 380-gram equivalency for three reasons. First, a review of the Commission's data indicated that the 380-gram equivalency was both the median and approximate mean ratio utilized by the courts when sentencing synthetic cathinone cases pursuant to Application Note 6. Thus, the Commission determined that the 380-gram equivalency best reflects the current sentencing practices for courts engaging in the Application Note 6 analysis.

Second, the Commission concluded that a ratio consistent with the existing methcathinone ratio was appropriate. The Commission set the methcathinone ratio based upon a scientific study that found that methcathinone was approximately 1.92 times more potent than amphetamine. At the time, amphetamine had a marihuana equivalency of 1:200, equivalent to the current marihuana equivalency of cocaine. The Commission's current study of cathinones did not uncover any new scientific evidence undermining its rationale for setting the methcathinone ratio.

Third, the Commission was presented with substantial information about synthetic cathinones' risks. Testimony before the Commission established that the effects and potencies of synthetic cathinones range from ''at least as dangerous as cocaine'' to methamphetamine-like. Medical experts discussed the substantial potential health impacts of cathinone use, while law enforcement witnesses offered reports of cathinone users' aggressive behavior posing threats to first responders. With cocaine at a 1:200 ratio and methamphetamine at a 1:2,000 ratio, the Commission concluded that the ratio of 1:380 minimized the risk of frequent over-punishment for substances in this class while providing penalty levels sufficient to account for the specific harms caused by distribution of these substances.

In adopting a class-based approach for both ease of application and because of the impracticability of listing every new substance in the class as it enters the market, the Commission recognizes, however, that some substances may be significantly more or less potent than the typical substances in the class that the ratio was intended to reflect. Therefore, the Commission added a departure provision to address those substances for which a greater or lesser quantity is needed to produce an effect on the central nervous system similar to the effect produced by a typical synthetic cathinone.

To provide guidance to the court in determining whether to apply the departure, the departure provision identifies substances that the Commission found to be fair representatives of the synthetic cathinones that would fall within the spectrum of substances included in the class, as well as those that may warrant a departure. Specifically, the departure provision notes that: A typical cathinone has a potency comparable to methcathinone or alpha-PVP; methylone is an example of a lower potency substance; and MDPV is an example of a higher potency substance.

Synthetic cannabinoids mimic the effects of tetrahydrocannabinol (''THC''), the main psychoactive chemical in marihuana. Unlike THC, however, most synthetic cannabinoids are ''full agonists.'' That is, they activate the body's type 1 cannabinoid receptors (CB_1) to a greater degree (*i.e.,* at 100%) than THC, which activates the CB_1 receptors only at 30 to 50 percent. Additionally, unlike THC, synthetic cannabinoids do not contain the additional substances that moderate their adverse effects. To the contrary, they may contain additional substances that augment their hallucinogenic effects. Further, some forms of packaged mixtures (*e.g.,* ''K2'', ''Spice'') may contain preservatives, additives, and other chemicals such as benzodiazepines that may compound the adverse effects caused by the cannabinoids. Also unlike THC, synthetic cannabinoids have been associated with physical harms such as organ failure and death.

Through the Commission's multi-year synthetic drug study, the Commission learned that hundreds of synthetic cannabinoids exist. When first marketed, synthetic cannabinoids generally have not yet been scheduled as controlled substances. Often, once a synthetic cannabinoid is scheduled, a new one is created to replace it. Given the large number of potential substances, the Commission found it impracticable to add individual marihuana equivalencies for every synthetic cannabinoid. In contrast, the Commission determined that a class-based approach for synthetic cannabinoids would be a better means to capture both current and future synthetic cannabinoids.

Based on hearing testimony, the scientific literature, and public comment, the Commission determined that all synthetic cannabinoids can be covered by a single class because these substances share a similar pharmacological effect: All synthetic cannabinoids bind to and activate the CB_1 receptor. Given the Commission's priority to alleviate the burdens associated with the Application Note 6 process and the impracticality of adding many new marihuana equivalencies, the Commission concluded the class-based approach strikes a middle ground between precision and ease of guideline application.

The amendment defines the term ''synthetic cannabinoid'' as ''any synthetic substance (other than synthetic tetrahydrocannabinol) that binds to and activates type 1 cannabinoid receptors (CB_1 receptors).'' The amendment establishes a marihuana equivalency for the class of synthetic cannabinoids of 1 gram of a synthetic cannabinoid (except a Schedule III, IV, or V substance) equals 167 grams of marihuana and applies a minimum base offense level of 12 to the class.

The marihuana equivalency selected for the class is identical to the existing marihuana equivalencies for both organic and synthetic tetrahydrocannabinol (THC). The Commission originally derived the organic and synthetic THC equivalencies from a comparison of standard dosage units of THC (3 mg) and marihuana (500 mg) and the relationship between the two, rather than the actual amount of THC commonly found in a dose of marihuana. During its current study, the Commission considered whether to incorporate THC (synthetic) into the new synthetic cannabinoid class. As

noted, the new synthetic cannabinoid class will be subject to the minimum base offense level of 12 applicable to most Schedule I and II controlled substances. The Commission set a minimum base offense level of 12 to the class for consistency with other Schedule I and II controlled substances. THC (synthetic) is not currently subject to the same minimum offense level. Thus, incorporating THC (synthetic) into the synthetic cannabinoid class would effectively change penalties for certain THC (synthetic) offenses, an outcome contrary to the Commission's intent. Consequently, THC (synthetic) is exempted from the class, its separate marihuana equivalency is retained, and that equivalency is applicable only in cases involving THC (synthetic).

Nevertheless, the Commission used the same marihuana equivalency for the class of synthetic cannabinoids. Commission data for cases involving synthetic cannabinoids indicates that the courts almost uniformly apply the marihuana equivalency for THC to such cases. Hence, the 1:167 ratio for the synthetic cannabinoid class reflects the courts' current sentencing practices. Although synthetic cannabinoids activate the CB_1 receptor to a greater degree than THC, the evidence also established that synthetic cannabinoids exhibit a range of potencies. Those most frequently encountered in the Commission's data exhibited potencies ranging from one to six times that of THC. Adoption of the existing THC marihuana equivalency minimizes the risk of frequent over-punishment for substances in this class while providing penalty levels that are sufficient to account for the specific harms caused by distribution of these substances.

Finally, the amendment provides two departure provisions addressing synthetic cannabinoids. First, the amendment provides for a departure based on the concentration of a synthetic cannabinoid. The Commission learned that synthetic cannabinoids are manufactured as a powder or crystalline substance and are typically sprayed on or mixed with inert material (such as plant matter) before retail sale. As a result, a synthetic cannabinoid seized after it has been prepared for retail sale will typically weigh significantly more than the undiluted form of the same controlled substance.

Given the central role of drug quantity in setting the base offense level, an individual convicted of an offense involving a synthetic cannabinoid mixture would likely be subject to a guideline penalty range significantly higher than another individual convicted of an offense involving an undiluted synthetic cannabinoid (but who could nevertheless produce an equivalent amount of consumable product). In a case involving undiluted synthetic cannabinoid, an upward departure may be appropriate for that reason. By contrast, in a case where the mixture containing synthetic cannabinoids contained a high quantity of inert material, a downward departure may be warranted.

The second departure provision provides that a downward departure may be appropriate where a substantially greater quantity of the synthetic cannabinoid involved in the offense is needed to produce an effect on the central nervous system similar to the effect produced by a typical synthetic cannabinoid in the class. The two synthetic cannabinoids specifically cited in the Commission's priority, JWH–018 and AM–2201, are three and a half times and five times more potent, respectively, than THC. If an offense involves a substantially less potent synthetic cannabinoid than JWH–018 or AM–2201, the court may wish to consider whether a downward departure is appropriate.

4. *Amendment:* The Commentary to § 1B1.10 captioned ''Application Notes'' is amended in Note 5 by striking ''Drug Equivalency Tables'' and inserting ''Drug Equivalency Tables (currently called Drug Conversion Tables)''.

Section 2D1.1(c)(1), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • 90,000 KG or more of *Converted Drug Weight.*''.

Section 2D1.1(c)(2), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 30,000 KG but less than 90,000 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(3), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 10,000 KG but less than 30,000 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(4), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 3,000 KG but less than 10,000 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(5), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 1,000 KG but less than 3,000 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(6), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 700 KG but less than 1,000 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(7), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 400 KG but less than 700 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(8), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 100 KG but less than 400 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(9), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 80 KG but less than 100 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(10), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 60 KG but less than 80 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(11), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 40 KG but less than 60 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(12), as amended by Amendment 3 of this document, is

further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 20 KG but less than 40 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(13), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Flunitrazepam and inserting a semicolon; and by adding at the end the following:

'' • At least 10 KG but less than 20 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(14), as amended by Amendment 3 of this document, is further amended by striking the period at the end of the line referenced to Schedule IV substances (except Flunitrazepam) and inserting a semicolon; and by adding at the end the following:

'' • At least 5 KG but less than 10 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(15) is amended by striking the period at the end of the line referenced to Schedule IV substances (except Flunitrazepam) and inserting a semicolon, and by adding at the end the following:

'' • At least 2.5 KG but less than 5 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(16) is amended by striking the period at the end of the line referenced to Schedule V substances and inserting a semicolon; and by adding at the end the following:

'' • At least 1 KG but less than 2.5 KG of *Converted Drug Weight.*''.

Section 2D1.1(c)(17) is amended by striking the period at the end of the line referenced to Schedule V substances and inserting a semicolon; and by adding at the end the following:

'' • Less than 1 KG of *Converted Drug Weight.*''.

The annotation to § 2D1.1(c) captioned ''Notes to Drug Quantity Table'', as amended by Amendment 3 of this document, is further amended by inserting at the end the following new Note (K):

''(K) The term 'Converted Drug Weight,' for purposes of this guideline, refers to a nominal reference designation that is used as a conversion factor in the Drug Conversion Tables set forth in the Commentary below, to determine the offense level for controlled substances that are not specifically referenced in the Drug Quantity Table or when combining differing controlled substances.''.

The Commentary to § 2D1.1 captioned ''Application Notes'', as amended by Amendment 3 of this document, is further amended—

in Note 6 by striking ''marihuana equivalency'' and inserting ''converted drug weight''; and by inserting after ''the most closely related controlled substance referenced in this guideline.'' the following: ''*See* Application Note 8.'';

in the heading of Note 8 by striking ''Drug Equivalency Tables'' and inserting ''Drug Conversion Tables'';

in Note 8(A) by striking ''Drug Equivalency Tables'' both places such term appears and inserting ''Drug Conversion Tables''; by striking ''to convert the quantity of the controlled substance involved in the offense to its equivalent quantity of marihuana'' and inserting ''to find the converted drug weight of the controlled substance involved in the offense''; by striking ''Find the equivalent quantity of marihuana'' and inserting ''Find the corresponding converted drug weight''; by striking ''Use the offense level that corresponds to the equivalent quantity of marihuana'' and inserting ''Use the offense level that corresponds to the converted drug weight determined above''; by striking ''an equivalent quantity of 5 kilograms of marihuana'' and inserting ''5 kilograms of converted drug weight''; and by striking ''the equivalent quantity of marihuana would be 500 kilograms'' and inserting ''the converted drug weight would be 500 kilograms'';

in Note 8(B) by striking ''Drug Equivalency Tables'' each place such term appears and inserting ''Drug Conversion Tables''; by striking ''convert each of the drugs to its marihuana equivalent'' and inserting ''convert each of the drugs to its converted drug weight''; by striking ''For certain types of controlled substances, the marihuana equivalencies'' and inserting ''For certain types of controlled substances, the converted drug weights assigned''; by striking ''*e.g.,* the combined equivalent weight of all Schedule V controlled substances shall not exceed 2.49 kilograms of marihuana'' and inserting ''*e.g.,* the combined converted weight of all Schedule V controlled substances shall not exceed 2.49 kilograms of converted drug weight''; by striking ''determine the marihuana equivalency for each schedule separately'' and inserting ''determine the converted drug weight for each schedule separately''; and by striking ''Then add the marihuana equivalencies to determine the combined marihuana equivalency'' and inserting ''Then add the converted drug weights to determine the combined converted drug weight'';

in Note 8(C)(i) by striking ''of marihuana'' each place such term appears and inserting ''of converted drug weight''; and by striking ''The total is therefore equivalent to 95 kilograms'' and inserting ''The total therefore converts to 95 kilograms'';

in Note 8(C)(ii) by striking the following:

''The defendant is convicted of selling 500 grams of marihuana (Level 6) and 10,000 units of diazepam (Level 6). The diazepam, a Schedule IV drug, is equivalent to 625 grams of marihuana. The total, 1.125 kilograms of marihuana, has an offense level of 8 in the Drug Quantity Table.'',

and inserting the following:

''The defendant is convicted of selling 500 grams of marihuana (Level 6) and 10,000 units of diazepam (Level 6). The marihuana converts to 500 grams of converted drug weight. The diazepam, a Schedule IV drug, converts to 625 grams of converted drug weight. The total, 1.125 kilograms of converted drug weight, has an offense level of 8 in the Drug Quantity Table.'';

in Note 8(C)(iii) by striking ''is equivalent'' both places such term appears and inserting ''converts''; by striking ''of marihuana'' each place such term appears and inserting ''of converted drug weight''; and by striking ''The total is therefore equivalent'' and inserting ''The total therefore converts'';

in Note 8(C)(iv) by striking ''marihuana equivalency'' each place such term appears and inserting ''converted drug weight''; by striking ''76 kilograms of marihuana'' and inserting ''76 kilograms''; by striking ''79.99 kilograms of marihuana'' both places such term appears and inserting ''79.99 kilograms of converted drug weight''; by striking ''equivalent weight'' each place such term appears and inserting ''converted weight''; by striking ''9.99 kilograms of marihuana'' and inserting ''9.99 kilograms''; and by striking ''2.49 kilograms of marihuana'' and inserting ''2.49 kilograms'';

in Note 8(D)—

in the heading, by striking ''Drug Equivalency Tables'' and inserting ''Drug Conversion Tables'';

under the heading relating to Schedule I or II Opiates, by striking the heading as follows:

''*Schedule I or II Opiates**'',

and inserting the following new heading:

''*Schedule I or II Opiates* Converted Drug Weight*'';

and by striking ''of marihuana'' each place such term appears;

under the heading relating Cocaine and Other Schedule I and II Stimulants (and their immediate precursors), by striking the heading as follows:

''*Cocaine and Other Schedule I and II Stimulants (and their immediate precursors)**'',

and inserting the following new heading:

''*Cocaine and Other Schedule I and II Stimulants (and their immediate precursors)** Converted Drug Weight*'';

and by striking ''of marihuana'' each place such term appears;

under the heading relating to Synthetic Cathinones (except Schedule III, IV, and V Substances), by striking the heading as follows:

''*Synthetic Cathinones (except Schedule III, IV, and V Substances)**'',

and inserting the following new heading:

''*Synthetic Cathinones (except Schedule III, IV, and V Substances)* Converted Drug Weight*'';

and by striking ''of marihuana'';

under the heading relating to LSD, PCP, and Other Schedule I and II Hallucinogens (and their immediate precursors), by striking the heading as follows:

''*LSD, PCP, and Other Schedule I and II Hallucinogens (and their immediate precursors)**'',

and inserting the following new heading:

''*LSD, PCP, and Other Schedule I and II Hallucinogens (and their immediate precursors)* Converted Drug Weight*'';

and by striking ''of marihuana'' each place such term appears;

under the heading relating to Schedule I Marihuana, by striking the heading as follows:

''*Schedule I Marihuana*'',

and inserting the following new heading:

''*Schedule I Marihuana Converted Drug Weight*'';

and by striking ''of marihuana'' each place such term appears;

under the heading relating to Synthetic Cannabinoids (except Schedule III, IV, and V Substances), by striking the heading as follows:

''*Synthetic Cannabinoids (except Schedule III, IV, and V Substances)**'',

and inserting the following new heading:

''*Synthetic Cannabinoids (except Schedule III, IV, and V Substances)* Converted Drug Weight*'';

and by striking ''of marihuana'';

under the heading relating to Flunitrazepam, by striking the heading as follows:

''*Flunitrazepam***'',

and inserting the following new heading:

''*Flunitrazepam** Converted Drug Weight*'';

and by striking ''of marihuana'';

under the heading relating to Schedule I or II Depressants (except gamma-hydroxybutyric acid), by striking the heading as follows:

''*Schedule I or II Depressants (except gamma-hydroxybutyric acid)*'',

and inserting the following new heading:

''*Schedule I or II Depressants (except gamma-hydroxybutyric acid) Converted Drug Weight*'';

and by striking ''of marihuana'';

under the heading relating to Gamma-hydroxybutyric Acid, by striking the heading as follows:

''*Gamma-hydroxybutyric Acid*'',

and inserting the following new heading:

''*Gamma-hydroxybutyric Acid Converted Drug Weight*'';

and by striking ''of marihuana'';

under the heading relating to Schedule III Substances (except ketamine), by striking the heading as follows:

''*Schedule III Substances (except ketamine)****'',

and inserting the following new heading:

''*Schedule III Substances (except ketamine)*** Converted Drug Weight*'';

by striking ''1 gm of marihuana'' and inserting ''1 gm''; by striking ''equivalent weight'' and inserting ''converted weight''; and by striking ''79.99 kilograms of marihuana'' and inserting ''79.99 kilograms of converted drug weight'';

under the heading relating to Ketamine, by striking the heading as follows:

''*Ketamine*'',

and inserting the following new heading:

''*Ketamine Converted Drug Weight*'';

and by striking ''of marihuana'';

under the heading relating to Schedule IV Substances (except flunitrazepam), by striking the heading as follows:

''*Schedule IV Substances (except flunitrazepam)*****'',

and inserting the following new heading:

''*Schedule IV Substances (except flunitrazepam)**** Converted Drug Weight*'';

by striking ''0.0625 gm of marihuana'' and inserting ''0.0625 gm''; and by striking ''*****Provided, that the combined equivalent weight of all Schedule IV (except flunitrazepam) and V substances shall not exceed 9.99 kilograms of marihuana.'' and inserting ''*****Provided, that the combined converted weight of all Schedule IV (except flunitrazepam) and V substances shall not exceed 9.99 kilograms of converted drug weight.'';

under the heading relating to Schedule V Substances, by striking the heading as follows:

''*Schedule V Substances******'',

and inserting the following new heading:

''*Schedule V Substances***** Converted Drug Weight*'';

by striking ''0.00625 gm of marihuana'' and inserting ''0.00625 gm''; and by striking ''******Provided, that the combined equivalent weight of Schedule V substances shall not exceed 2.49 kilograms of marihuana.'' and inserting ''*****Provided, that the combined converted weight of Schedule V substances shall not exceed 2.49 kilograms of converted drug weight.'';

under the heading relating to List I Chemicals (relating to the manufacture of amphetamine or methamphetamine), by striking the heading as follows:

''*List I Chemicals (relating to the manufacture of amphetamine or methamphetamine)*******'',

and inserting the following new heading:

''*List I Chemicals (relating to the manufacture* of amphetamine or methamphetamine)****** *Converted Drug Weight*'';

by striking ''of marihuana'' each place such term appears; and by striking ''*******Provided, that in a case involving'' and inserting ''******Provided, that in a case involving'';

under the heading relating to Date Rape Drugs (except flunitrazepam, GHB, or ketamine), by striking the heading as follows:

''*Date Rape Drugs (except flunitrazepam, GHB, or ketamine)*'',

and inserting the following new heading:

''*Date Rape Drugs (except flunitrazepam, GHB, or ketamine) Converted Drug Weight*'';

and by striking ''marihuana'' both places such term appears;

and in the text before the heading relating to Measurement Conversion Table, by striking ''To facilitate

conversions to drug equivalencies'' and inserting ''To facilitate conversions to converted drug weight'';

in Note 27(D) by striking ''marihuana equivalencies'' both place such term appears and inserting ''converted drug weights''; by striking ''Drug Equivalency Tables'' and inserting ''Drug Conversion Tables''; and by striking ''marihuana equivalency'' and inserting ''converted drug weight'';

and in Note 27(E)(ii) by striking ''marihuana equivalency'' and inserting ''converted drug weight''.

The Commentary to § 2D1.1 captioned ''Background'', as amended by Amendment 3 of this document, is further amended by adding at the end the following new paragraph:

''The Drug Conversion Tables set forth in Application Note 8 were previously called the Drug Equivalency Tables. In the original 1987 *Guidelines Manual,* the Drug Equivalency Tables provided four conversion factors (or 'equivalents') for determining the base offense level in cases involving either a controlled substance not referenced in the Drug Quantity Table or multiple controlled substances: heroin, cocaine, PCP, and marihuana. In 1991, the Commission amended the Drug Equivalency Tables to provide for one substance, marihuana, as the single conversion factor in § 2D1.1. *See* USSG App. C, Amendment 396 (effective November 1, 1991). In 2018, the Commission amended § 2D1.1 to replace marihuana as the conversion factor with the new term 'converted drug weight' and to change the title of the Drug Equivalency Tables to the 'Drug Conversion Tables.' ''.

The Commentary to § 2D1.11 captioned ''Application Notes'' is amended in Note 9 by striking ''Drug Equivalency Table'' and inserting ''Drug Conversion Table''.

The Concluding Commentary to Part D of Chapter Three is amended in Example 2 by striking ''marihuana equivalents'' and inserting ''converted drug weight''; by striking ''Drug Equivalency Tables'' and inserting ''Drug Conversion Tables''; and by striking ''of marihuana'' each place such term appears and inserting ''of converted drug weight''.

Reason for Amendment: This amendment makes technical changes to § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy). It replaces the term ''marihuana equivalency,'' which is used in the Drug Equivalency Tables for determining penalties for controlled substances that are not specifically referenced in the Drug Quantity Table or when combining differing controlled substances, with the term ''converted drug weight.''

The Commission received comment expressing concern that the term ''marihuana equivalency'' is misleading and results in confusion for individuals not fully versed in the guidelines. Some commenters suggested that the Commission should replace ''marihuana equivalency'' with another term.

Specifically, the amendment adds the new term ''converted drug weight'' to all provisions of the Drug Quantity Table at § 2D1.1(c) and changes the title of the ''Drug Equivalency Tables'' to ''Drug Conversion Tables.'' In addition, the amendment makes technical changes throughout the *Guidelines Manual* to account for the new term.

This amendment is not intended as a substantive change in policy for § 2D1.1.

5. *Amendment:* Section 2L1.2(b)(2) is amended by striking ''If, before the defendant was ordered deported or ordered removed from the United States for the first time, the defendant sustained—'' and inserting ''If, before the defendant was ordered deported or ordered removed from the United States for the first time, the defendant engaged in criminal conduct that, at any time, resulted in—''.

Section 2L1.2(b)(3) is amended by striking ''If, at any time after the defendant was ordered deported or ordered removed from the United States for the first time, the defendant engaged in criminal conduct resulting in—'' and inserting ''If, after the defendant was ordered deported or ordered removed from the United States for the first time, the defendant engaged in criminal conduct that, at any time, resulted in—''.

The Commentary to § 2L1.2 captioned ''Application Notes'' is amended—

in Note 2 in the paragraph that begins '''Sentence imposed' has the meaning'' by striking ''includes any term of imprisonment given upon revocation of probation, parole, or supervised release'' and inserting ''includes any term of imprisonment given upon revocation of probation, parole, or supervised release, regardless of when the revocation occurred'';

in Note 4 by striking ''subsection (b)(3),'' and inserting ''subsection (b)(2) or (b)(3), as appropriate,'';

and by redesignating Notes 5 through 7 as Notes 6 through 8, respectively; and by inserting the following new Note 5:

''5. *Cases in Which the Criminal Conduct Underlying a Prior Conviction Occurred Both Before and After the Defendant Was First Ordered Deported or Ordered Removed.*—There may be cases in which the criminal conduct underlying a prior conviction occurred both before and after the defendant was ordered deported or ordered removed from the United States for the first time. For purposes of subsections (b)(2) and (b)(3), count such a conviction only under subsection (b)(2).''

Reason for Amendment: This amendment responds to two application issues that arose after § 2L1.2 (Unlawfully Entering or Remaining in the United States) was extensively amended in 2016. *See* USSG, App. C, Amendment 802 (effective Nov. 1, 2016).

The specific offense characteristic at § 2L1.2(b)(2) applies a sliding scale of enhancements, based on sentence length, if the ''defendant sustained'' a ''conviction'' before being ordered removed for the first time. Correspondingly, § 2L1.2(b)(3) applies a parallel scale of enhancements if the defendant ''engaged in criminal conduct resulting in'' a conviction ''at any time after'' the first order of removal. In most situations, any prior felony conviction that received criminal history points will qualify under either subsection (b)(2) or (b)(3), with the extent of the increase depending on the length of the sentence imposed. In some scenarios, a felony will not qualify for an upward adjustment under either subsection (b)(2) or (b)(3) even though it received criminal history points. Those scenarios occur when a defendant committed a crime before being ordered removed for the first time but was not convicted (or sentenced) for that crime until after that first order of removal.

The amendment addresses this issue by establishing that the application of the § 2L1.2(b)(2) enhancement depends on the timing of the underlying ''criminal conduct,'' and not on the timing of the resulting conviction. It does so by amending the first paragraph of subsection (b)(2) to state that the enhancement applies if pre-first removal conduct resulted in a conviction ''at any time,'' and makes a conforming change to the first paragraph of subsection (b)(3). In order to address how to treat an offense involving conduct that occurred both before and after a defendant's first order of removal, the amendment adds a new Application Note 5 explaining that an offense involving such conduct should be counted only under subsection (b)(2). The Commission determined that a defendant with a prior non-illegal reentry felony conviction that received criminal history points should receive

an enhancement for that conviction under either subsection (b)(2) or (b)(3). A defendant should not avoid an enhancement for an otherwise qualifying conviction because the conviction occurred after a defendant's first order of removal or deportation but was premised on conduct that occurred before that order. Because a conviction could be premised on conduct that occurred both before and after the first order of removal or deportation, the Commission adopted Application Note 5 to explain that such convictions are only counted once, under subsection (b)(2).

The specific offense characteristics at § 2L1.2(b)(2) and (b)(3) increase a defendant's offense level based on the length of the ''sentence imposed'' for a prior felony conviction. An application note defines ''sentence imposed'' to mean ''sentence of imprisonment'' as that term is used in the criminal history guideline, § 4A1.2. *See* USSG § 2L1.2, comment. (n.2.). Consistent with that definition, the application note also directs that ''[t]he length of the sentence imposed includes any term of imprisonment given upon revocation of probation, parole, or supervised release.'' *Id.*

Another part of the commentary to § 2L1.2 directs that only convictions receiving criminal history points under ''§ 4A1.1(a), (b), or (c)'' (which assign points based on the length of the prior sentence imposed) are to be counted under § 2L1.2(b). *See* USSG § 2L1.2, comment. (n.3). In determining the length of a sentence for purposes of Chapter Four (and thus the number of criminal history points to be applied), the length of any term imposed on revocation of probation, parole, supervised release, or other similar status is added to the original term of imprisonment and the total term is used to calculate criminal history points under § 4A1.1(a), (b), or (c). *See* USSG § 4A1.2(k)(1).

A Fifth Circuit opinion interpreted § 2L1.2(b)(2) to bar consideration of a revocation that did not occur until *after* a defendant's first order of removal, even if the defendant was convicted prior to the first order of the removal. *See United States* v. *Franco-Galvan,* 864 F.3d 338 (5th Cir. 2017). The court found that Application Note 2, despite its instruction that ''the length of the sentence imposed includes any term of imprisonment given upon revocation of probation, parole, or supervised release,'' was insufficiently clear to resolve the ''temporal'' question of when a revocation must occur, given that the Commission had resolved a prior circuit conflict in 2012 by directing that revoked time should not be counted in the situation. *See* USSC, App. C, Amendment 764 (effective Nov. 1, 2012). A subsequent decision of the Ninth Circuit reached the same result. *See United States* v. *Martinez,* 870 F.3d 1163 (9th Cir. 2017). Although both cases involved an enhancement under subsection (b)(2), the same logic would seem to apply to enhancements under subsection (b)(3) when the conviction and revocation were separated by an intervening order of removal or deportation.

The amendment resolves this issue by adding the clarifying phrase ''regardless of when the revocation occurred'' to the definition of ''sentence imposed'' in Application Note 2. The Commission determined that, consistent with the purposes of the 2016 amendment to § 2L1.2, the data underlying it, and the statement in Application Note 2, the length of a sentence imposed for purposes of § 2L1.2(b)(2) and (b)(3) should include any additional term of imprisonment imposed upon revocation of probation, suspended sentence, or supervised release, regardless of whether the revocation occurred before or after the defendant's first (or any subsequent) order of removal. As the reason for amendment for Amendment 802 explained, ''[t]he Commission determined that a sentence-imposed approach is consistent with the Chapter Four criminal history rules, easily applied, and appropriately calibrated to account for the seriousness of prior offenses.'' USSC, App. C, Amendment 802 (effective Nov. 1, 2016). Excluding sentence length added by post-removal revocations would be inconsistent with the purpose of Amendment 802 and its underlying data analysis. *Id.*

6. *Amendment:* The Commentary to § 3E1.1 captioned ''Application Notes'' is amended in Note 1(A) by striking ''However, a defendant who falsely denies, or frivolously contests, relevant conduct that the court determines to be true has acted in a manner inconsistent with acceptance of responsibility'' and inserting ''A defendant who falsely denies, or frivolously contests, relevant conduct that the court determines to be true has acted in a manner inconsistent with acceptance of responsibility, but the fact that a defendant's challenge is unsuccessful does not necessarily establish that it was either a false denial or frivolous''.

Reason for Amendment: This amendment responds to concerns that some courts have interpreted the commentary to § 3E1.1 (Acceptance of Responsibility) to automatically preclude application of the 2-level reduction for acceptance of responsibility when the defendant makes an unsuccessful good faith, non-frivolous challenge to relevant conduct. Application Note 1 provides a non-exhaustive list of appropriate considerations in determining whether a defendant has clearly demonstrated acceptance of responsibility. Among those considerations is whether the defendant truthfully admitted the conduct comprising the offense(s) of conviction and truthfully admitted or did not falsely deny any additional relevant conduct for which the defendant is accountable under § 1B1.3 (Relevant Conduct). *See* USSG § 3E1.1, comment. (n.1(A)). The application note further provides that ''a defendant who falsely denies, or frivolously contests, relevant conduct that the court determines to be true has acted in a manner inconsistent with acceptance of responsibility.'' The amendment clarifies that an unsuccessful challenge to relevant conduct does not necessarily establish that the challenge was either a false denial or frivolous. Specifically, the amendment adds ''but the fact that a defendant's challenge is unsuccessful does not necessarily establish that it was either a false denial or frivolous'' to the end of Application Note 1(A).

7. *Amendment:* The Commentary to § 5C1.1 captioned ''Application Notes'' is amended by redesignating Notes 4 through 9 as Notes 5 through 10, respectively; and by inserting the following new Note 4:

''4. If the defendant is a nonviolent first offender and the applicable guideline range is in Zone A or B of the Sentencing Table, the court should consider imposing a sentence other than a sentence of imprisonment, in accordance with subsection (b) or (c)(3). *See* 28 U.S.C. 994(j). For purposes of this application note, a 'nonviolent first offender' is a defendant who has no prior convictions or other comparable judicial dispositions of any kind and who did not use violence or credible threats of violence or possess a firearm or other dangerous weapon in connection with the offense of conviction. The phrase 'comparable judicial dispositions of any kind' includes diversionary or deferred dispositions resulting from a finding or admission of guilt or a plea of *nolo contendere* and juvenile adjudications.''.

The Commentary to § 5F1.2 captioned ''Application Notes'' is amended in Note 1 by striking ''Electronic monitoring is an appropriate means of surveillance and ordinarily should be used in connection with home detention'' and inserting ''Electronic monitoring is an appropriate means of

surveillance for home detention''; and by striking ''alternative means of surveillance may be used so long as they are as effective as electronic monitoring'' and inserting ''alternative means of surveillance may be used if appropriate''.

The Commentary to § 5F1.2 captioned ''Background'' is amended by striking ''The Commission has concluded that the surveillance necessary for effective use of home detention ordinarily requires electronic monitoring'' and inserting ''The Commission has concluded that electronic monitoring is an appropriate means of surveillance for home detention''; and by striking ''the court should be confident that an alternative form of surveillance will be equally effective'' and inserting ''the court should be confident that an alternative form of surveillance is appropriate considering the facts and circumstances of the defendant's case''.

Section 5H1.3 is amended by striking ''*See* § 5C1.1, Application Note 6'' and inserting ''*See* § 5C1.1, Application Note 7''.

Section 5H1.4 is amended by striking ''*See* § 5C1.1, Application Note 6'' and inserting ''*See* § 5C1.1, Application Note 7''.

Reason for Amendment: The amendment adds a new application note to the Commentary at § 5C1.1 (Imposition of a Term of Imprisonment), which states that if a defendant is a ''nonviolent first offender and the applicable guideline range is in Zone A or B of the Sentencing Table, the court should consider imposing a sentence other than a sentence of imprisonment.'' This new application note is consistent with the statutory language in 28 U.S.C. 994(j) regarding the ''general appropriateness of imposing a sentence other than imprisonment'' for ''a first offender who has not been convicted of a crime of violence or an otherwise serious offense'' and cites the statutory provision in support. It also is consistent with a recent Commission recidivism study, which demonstrated that offenders with zero criminal history points have a lower recidivism rate than offenders with one criminal history point, and that offenders with zero criminal history points and no prior contact with the criminal justice system have an even lower recidivism rate. *See* Tracey Kyckelhahn & Trishia Cooper, U.S. Sentencing Comm'n, *The Past Predicts the Future: Criminal History and Recidivism of Federal Offenders* at 6–9 (2017).

Where permitted by statute, the *Guidelines Manual* provides for non-incarceration sentences for offenders in Zones A and B of the Sentencing Table. Zone A (in which all sentencing ranges are zero to six months regardless of criminal history category) permits the full spectrum of sentencing options: (1) A fine only; (2) a term of probation only; (3) probation with conditions of confinement (home detention, community confinement, or intermittent confinement); (4) a ''split sentence'' (a term of imprisonment followed by a term of supervised release with condition of confinement that substitutes for a portion of the guideline term); or (5) a term of imprisonment only. Zone B (which includes sentencing ranges that have a low-end of one month and a high-end of 15 months, and vary by criminal history category) also authorizes non-prison sentences. However, Zone B sentencing options are more restrictive, authorizing (1) probation with conditions of confinement; (2) a ''split sentence''; or (3) a term of imprisonment only. Consistent with the statutory mandate in section 994(j), the application note is intended to serve as a reminder to courts to consider imposing non-incarceration sentences for a defined class of ''nonviolent first offenders'' whose applicable guideline ranges are in Zones A or B of the Sentencing Table.

For purposes of the new application note, the amendment defines a ''nonviolent first offender'' as a defendant who (1) has no prior convictions or other comparable judicial dispositions of any kind; and (2) did not use violence or credible threats of violence or possess a firearm or other dangerous weapon in connection with the offense. It explains that ''comparable judicial dispositions of any kind'' includes ''diversionary or deferred dispositions resulting from a finding or admission of guilt or a plea of *nolo contendere* and juvenile adjudications.''

The amendment adopts language from the statutory and guidelines ''safety-valve'' provisions to exclude offenders who ''use[d] violence or credible threats of violence or possess[ed] a firearm or other dangerous weapon in connection with the offense.'' *See* 18 U.S.C. 3553(f)(2); USSG § 5C1.2(a)(2). This real-offense definition of ''violent'' offense avoids the complicated application of the ''categorical approach'' to determine whether an offense qualifies as ''violent.'' *See United States* v. *Starks,* 861 F.3d 306, 324 (1st Cir. 2017) (describing the ''immensely complicated analysis required by the categorical approach''); *see also* USSG § 5C1.2, comment. (n.3) (noting that the determination of whether ''the offense'' was violent or involved a firearm requires a court to consider not only the offense of conviction but also ''all relevant conduct''). It also ensures that only nonviolent offenders are covered by the new application note.

The amendment also deletes language from the commentary to § 5F1.2 (Home Detention) that generally encouraged courts to use electronic monitoring (also called location monitoring) when home detention is made a condition of supervision, and instead instructs that electronic monitoring or any alternative means of surveillance may each be used, as ''appropriate.'' The goal of this change is to increase the use of probation with home detention as an alternative to incarceration. The Commission received testimony indicating that location monitoring is resource-intensive and otherwise demanding on probation officers. Additionally, it heard testimony that imposing location monitoring by default is inconsistent with the evidence-based ''risk-needs-responsivity'' (RNR) model of supervision and may be counterproductive for certain lower-risk offenders. For many low-risk offenders, less intensive surveillance methods (*e.g.,* telephonic contact, video conference, unannounced home visits by probation officers) are sufficient to enforce home detention. The revised language would allow probation officers and courts to exercise discretion to use surveillance methods that they deem appropriate in light of evidence-based practices.

8. *Amendment:* The Commentary to § 2A3.5 captioned ''Statutory Provision'' is amended by striking ''§ 2250(a)'' and inserting ''§ 2250(a), (b)''.

The Commentary to § 2A3.5 captioned ''Application Notes'' is amended by redesignating Note 2 as Note 3; and by inserting the following new Note 2:

''2. *Application of Subsection (b)(1).*— For purposes of subsection (b)(1), a defendant shall be deemed to be in a 'failure to register status' during the period in which the defendant engaged in conduct described in 18 U.S.C. 2250(a) or (b).''.

Section 2A3.6(a) is amended by striking ''§ 2250(c)'' and inserting ''§ 2250(d)''.

The Commentary to § 2A3.6 captioned ''Statutory Provisions'' is amended by striking ''2250(c)'' and inserting ''2250(d)''.

The Commentary to § 2A3.6 captioned ''Application Notes'' is amended—

in Note 1 by striking ''Section 2250(c)'' and inserting ''Section 2250(d)''; and by inserting after ''18 U.S.C. 2250(a)'' the following: ''or (b)'';

in Note 3 by striking ''§ 2250(c)'' and inserting ''§ 2250(d)'';

and in Note 4 by striking ''§ 2250(c)'' and inserting ''§ 2250(d)''.

Section 2B5.3(b)(5) is amended by striking ''counterfeit drug'' and inserting ''drug that uses a counterfeit mark on or in connection with the drug''.

The Commentary to § 2B5.3 captioned ''Application Notes'' is amended in Note 1 by striking the third undesignated paragraph as follows:

'' 'Counterfeit drug' has the meaning given that term in 18 U.S.C. 2320(f)(6).'';

and by inserting after the paragraph that begins '' 'Counterfeit military good or service' has the meaning'' the following new paragraph:

'' 'Drug' and 'counterfeit mark' have the meaning given those terms in 18 U.S.C. 2320(f).''.

The Commentary to § 2G1.3 captioned ''Application Notes'' is amended in Note 4 by striking ''(b)(3)'' each place such term appears and inserting ''(b)(3)(A)''.

Section 5D1.3(a)(6)(A) is amended by striking ''18 U.S.C. 2248, 2259, 2264, 2327, 3663, 3663A, and 3664'' and inserting ''18 U.S.C. 3663 and 3663A, or any other statute authorizing a sentence of restitution''.

Appendix A (Statutory Index) is amended—

in the line referenced to 15 U.S.C. 2615 by striking ''§ 2615'' and inserting ''§ 2615(b)(1)'';

by inserting before the line referenced to 15 U.S.C. 6821 the following new line reference:

''15 U.S.C. 2615(b)(2) 2Q1.1'';

in the line referenced to 18 U.S.C. 2250(a) by striking ''§ 2250(a)'' and inserting ''§ 2250(a), (b)'';

and in the line referenced to 18 U.S.C. 2250(c) by striking ''§ 2250(c)'' and inserting ''§ 2250(d)''.

Reason for Amendment: This multi-part amendment responds to recently enacted legislation and miscellaneous guideline application issues.

First, the amendment responds to section 6 of the International Megan's Law to Prevent Child Exploitation and Other Sexual Crimes Through Advanced Notification of Traveling Sex Offenders, Public Law 114–119 (Feb. 8, 2016), which added a new registration requirement for certain sex offenders required to register under the Sex Offender Registration and Notification Act (SORNA) at 34 U.S.C. 20914. SORNA requires sex offenders to register in the sex offender registry, and keep their registration current, by providing certain identifying information including names, addresses, and Social Security Numbers. The new requirement at 34 U.S.C. 20914(7) directs sex offenders to provide information relating to intended travel outside the United States, including any anticipated dates and places of departure, arrival or return, air carrier and flight numbers, and destination country. The Act also established a new offense at 18 U.S.C. 2250(b). For those required to register under SORNA, knowingly failing to provide this travel-related information and engaging or attempting to engage in the intended travel outside of the United States, carries a statutory maximum of 10 years of imprisonment. Section 2250 offenses are referenced in Appendix A (Statutory Index) to § 2A3.5 (Failure to Register as a Sex Offender). The amendment amends Appendix A so the new offense at 18 U.S.C. 2250(b) is referenced to § 2A3.5. The amendment also adds a new Application Note 2 to the Commentary to § 2A3.5 providing that for purposes of § 2A3.5(b)(1), a defendant shall be considered in a ''failure to register status'' during the time the defendant engaged in conduct described in either section 2250(a) (failing to register or update registration) or section 2250(b) (failing to provide required travel-related information). This application note reflects the Commission's determination that failing to provide information about intended foreign travel meets the definition of failing to update registration information in the sex offender registry. In addition, the amendment makes clerical changes to § 2A3.6 (Aggravated Offenses Relating to Registration as a Sex Offender) to reflect the adoption of section 2250(b) and the associated redesignation of section 2250(c) as section 2250(d).

Second, the amendment responds to section 3 of the Transnational Drug Trafficking Act of 2016, Public Law 114–154 (May 16, 2016), which made changes relating to the trafficking of counterfeit drugs by amending the language in the penalty provision at 18 U.S.C. 2320. The Act amended section 2320(b)(3) to replace the term ''counterfeit drug'' with the phrase ''a drug that uses a counterfeit mark on or in connection with the drug.'' The Act also revised section 2320(f) to define the term ''drug'' by reference to the term as defined in the Federal Food, Drug, and Cosmetic Act found at 21 U.S.C. 321. Section 2320 offenses are referenced in Appendix A (Statutory Index) to § 2B5.3 (Criminal Infringement of Copyright or Trademark). The amendment replaces the term ''counterfeit drug'' at § 2B5.3(b)(5) with the new phrase in the revised section 2320(b)(3), to remain consistent with the language of the statute. Similarly, the amendment amends the commentary to § 2B5.3 to remove a definition for the obsolete term ''counterfeit drug'' and replace it with definitions of the terms ''drug'' and ''counterfeit mark'' as found in the revised statute.

Third, the amendment responds to section 12 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016, Public Law 114–182 (June 22, 2016), which amended section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) by adding a new provision at section 2615(b)(2). The new provision prohibits any person from knowingly and willfully violating specific provisions of the Toxic Substances Control Act, knowing at the time of the violation that the violation puts a person in imminent danger of death or bodily injury, with a maximum penalty of 15 years of imprisonment. The Toxic Substances Control Act is referenced in Appendix A (Statutory Index) to § 2Q1.2 (Mishandling of Hazardous or Toxic Substances of Pesticides; Recordkeeping, Tampering, and Falsification; Unlawfully Transporting Hazardous Materials in Commerce). The amendment continues to reference the preexisting offense, now codified at section 2615(b)(1), to § 2Q1.2, but references the new offense, codified at section 2615(b)(2), to § 2Q1.1 (Knowing Endangerment Resulting From Mishandling Hazardous or Toxic Substances, Pesticides or Other Pollutants). The Commission determined § 2Q1.1 is the most analogous guideline because it covers similar ''knowing endangerment'' provisions and has a similar *mens rea* element found in similar statutes referenced in Appendix A to § 2Q1.1.

Fourth, the amendment responds to section 2 of the Justice for All Reauthorization Act of 2016, Public Law 114–324 (Dec. 16, 2016), which amended 18 U.S.C. 3583(d) (relating to conditions of supervised release) to require a court, when imposing a sentence of supervised release, to include as a condition that the defendant make restitution in accordance with sections 3663 and 3663A of Title 18 of the United States Code, or any other statute authorizing a sentence of restitution. The amendment amends subsection (a)(6)(A) of § 5D1.3 (Conditions of Supervised Release) to include a mandatory condition of supervised release in conformance with the new statutory requirement. The amendment also parallels the Judicial Conference of the United States' recent revision of the Judgment in a Criminal Case form to include a new mandatory condition of supervised release.

Fifth, the amendment clarifies an application issue that has arisen with respect to § 2G1.3 (Promoting a Commercial Sex Act or Prohibited Sexual Conduct with a Minor; Transportation of Minors to Engage in a Commercial Sex Act or Prohibited Sexual Conduct; Travel to Engage in Commercial Sex Act or Prohibited Sexual Conduct with a Minor; Sex Trafficking of Children; Use of Interstate Facilities to Transport Information about a Minor), which applies to several offenses involving the transportation of a minor for illegal sexual activity. A two-level enhancement at § 2G1.3(b)(3) applies if the offense involved the use of a computer to either (A) persuade, entice or coerce a minor, or to facilitate the travel of a minor, to engage in prohibited sexual conduct, or (B) to entice, offer, or solicit a person to engage in prohibited sexual conduct with a minor. While Application Note 4 sets forth guidance on this enhancement, it fails to distinguish between the two prongs of subsection (b)(3). As a result, an application issue has arisen regarding whether the note prohibits application of the enhancement where a computer was used to solicit a third party to engage in prohibited sexual conduct with a minor, as set out in subsection (b)(3)(B). Courts have concluded that the application note is inconsistent with the language of § 2G1.3(b)(3), and that application of the enhancement for the use of a computer in third party solicitation cases is proper. *See e.g., United States* v. *Cramer,* 777 F.3d 597, 606 (2d Cir. 2015); *United States* v. *McMillian,* 777 F.3d 444, 449–50 (7th Cir. 2015); *United States* v. *Hill,* 782 F.3d 842, 846 (11th Cir. 2015); *United States* v. *Pringler,* 765 F.3d 455 (5th Cir. 2014). The amendment is intended to clarify the Commission's original intent that Application Note 4 apply only to subsection (b)(3)(A).

9. *Amendment:* Chapter One, Part A is amended—

in Subpart 1(4)(b) (Departures) by inserting an asterisk after ''§ 5K2.19 (Post-Sentencing Rehabilitative Efforts)''; and by inserting after the first paragraph the following note:

''*Note: Section 5K2.19 (Post-Sentencing Rehabilitative Efforts) was deleted by Amendment 768, effective November 1, 2012. (*See* USSG App. C, amendment 768.)'';

and in the note at the end of Subpart 1(4)(d) (Probation and Split Sentences) by striking ''Supplement to Appendix C'' and inserting ''USSG App. C''.

The Commentary to § 1B1.13 captioned ''Application Notes'' is amended in Note 4 by striking ''factors set forth 18 U.S.C. 3553(a)'' and inserting ''factors set forth in 18 U.S.C. 3553(a)''.

The Commentary to § 2A3.5 captioned ''Application Notes'' is amended in Note 1 in the paragraph that begins '' 'Sex offense' has the meaning'' by striking ''42 U.S.C. 16911(5)'' and inserting ''34 U.S.C. 20911(5)''; and in the paragraph that begins '' 'Tier I offender', 'Tier II offender', and 'Tier III offender' have the meaning'' by striking ''42 U.S.C. 16911'' and inserting ''34 U.S.C. 20911''.

The Commentary to § 2B1.1 captioned ''Application Notes'' is amended in Note 2(A)(i) by striking ''as determined under the provisions of § 1B1.2 (Applicable Guidelines) for the offense of conviction'' and inserting the following: ''specifically referenced in Appendix A (Statutory Index) for the offense of conviction, as determined under the provisions of § 1B1.2 (Applicable Guidelines)''.

The Commentary to § 2B1.5 captioned ''Application Notes'' is amended—

in Note 1(A) by striking clause (ii) and redesignating clauses (iii) through (vii) as clauses (ii) through (vi), respectively;

in Note 1(A)(i) by striking ''16 U.S.C. 470w(5)'' and inserting ''54 U.S.C. 300308'';

in Note 3(C) by striking ''16 U.S.C. 470a(a)(1)(B)'' and inserting ''54 U.S.C. 302102'';

in Note 3(E) by striking ''the Antiquities Act of 1906 (16 U.S.C. 431)'' and inserting ''54 U.S.C. 320301'';

and in Note 3(F) by striking ''16 U.S.C. 1c(a)'' and inserting ''54 U.S.C. 100501''.

Section 2D1.11 is amended in subsection (d)(6) by striking ''Pseuodoephedrine'' and inserting ''Pseudoephedrine''; and in subsection (e)(2), under the heading relating to List I Chemicals, by striking the period at the end and inserting a semicolon.

The Commentary to § 2M2.1 captioned ''Statutory Provisions'' is amended by striking ''§ 2153'' and inserting ''§§ 2153''; and by inserting at the end the following: ''For additional statutory provision(s), *see* Appendix A (Statutory Index).''.

The Commentary to § 2Q1.1 captioned ''Statutory Provisions'' is amended by striking ''42 U.S.C. 6928(e)'' and inserting ''42 U.S.C. 6928(e), 7413(c)(5)''; and by inserting at the end the following: ''For additional statutory provision(s), *see* Appendix A (Statutory Index).''.

The Commentary to § 2Q1.2 captioned ''Statutory Provisions'' is amended by striking ''7413'' and inserting ''7413(c)(1)–(4)''.

The Commentary to § 2Q1.3 captioned ''Statutory Provisions'' is amended by striking ''7413'' and inserting ''7413(c)(1)–(4)''.

The Commentary to § 2Q1.3 captioned ''Application Notes'' is amended in Note 8 by striking ''Adequacy of Criminal History Category'' and inserting ''Departures Based on Inadequacy of Criminal History Category (Policy Statement)''.

The Commentary to § 2R1.1 captioned ''Application Notes'' is amended in Note 7 by striking ''Adequacy of Criminal History Category'' and inserting ''Departures Based on Inadequacy of Criminal History Category (Policy Statement)''.

The Commentary to § 2X5.2 captioned ''Statutory Provisions'' is amended by striking ''42 U.S.C. 14133'' and inserting ''34 U.S.C. 12593''.

Section 4A1.2 is amended in subsections (h), (i), and (j) by striking ''Adequacy of Criminal History Category'' each place such term appears and inserting ''Departures Based on Inadequacy of Criminal History Category (Policy Statement)''.

The Commentary to § 4A1.2 captioned ''Application Notes'' is amended in Notes 6 and 8 by striking ''Adequacy of Criminal History Category'' both places such term appears and inserting ''Departures Based on Inadequacy of Criminal History Category (Policy Statement)''.

The Commentary to § 4B1.4 captioned ''Background'' is amended by striking ''Adequacy of Criminal History Category'' and inserting ''Departures Based on Inadequacy of Criminal History Category (Policy Statement)''.

Section 5B1.3(a)(10) is amended by striking ''42 U.S.C. 14135a'' and inserting ''34 U.S.C. 40702''.

Section 5D1.3 is amended in subsection (a)(4) by striking ''release on probation'' and inserting ''release on supervised release''; and in subsection (a)(8) by striking ''42 U.S.C. 14135a'' and inserting ''34 U.S.C. 40702''.

Section 8C2.1(a) is amended by striking ''§§ 2C1.1, 2C1.2, 2C1.6'' and inserting ''§§ 2C1.1, 2C1.2''.

Appendix A (Statutory Index) is amended—

by striking the line referenced to 16 U.S.C. 413;

in the line referenced to 18 U.S.C. 371 by rearranging the guidelines to place them in proper numerical order;

in the line referenced to 18 U.S.C. 1591 by rearranging the guidelines to place them in proper numerical order;

by inserting after the line referenced to 18 U.S.C. 1864 the following new line reference:

''18 U.S.C. 1865(c)	2B1.1'';

by inserting after the line referenced to 33 U.S.C. 3851 the following new line references:

''34 U.S.C. 10251	2B1.1
34 U.S.C. 10271	2B1.1
34 U.S.C. 12593	2X5.2
34 U.S.C. 20962	2H3.1
34 U.S.C. 20984	2H3.1'';

and by striking the lines referenced to 42 U.S.C. 3791, 42 U.S.C. 3795, 42 U.S.C. 14133, 42 U.S.C. 16962, and 42 U.S.C. 16984.

Reason for Amendment: This amendment makes various technical changes to the *Guidelines Manual.*

First, the amendment sets forth clarifying changes to two guidelines. The amendment amends Chapter One, Part A, Subpart 1(4)(b) (Departures) to provide an explanatory note addressing the fact that § 5K2.19 (Post-Sentencing Rehabilitative Efforts) was deleted by Amendment 768, effective November 1, 2012. The amendment also makes minor clarifying changes to Application Note 2(A) to § 2B1.1 (Theft, Property Destruction, and Fraud), to make clear that, for purposes of subsection (a)(1)(A), an offense is ''referenced to this guideline'' if § 2B1.1 is the applicable Chapter Two guideline specifically referenced in Appendix A (Statutory Index) for the offense of conviction.

Second, the amendment makes technical changes to provide updated references to certain sections in the United States Code that were restated in legislation. As part of an Act to codify existing law relating to the National Park System, Congress repealed numerous sections in Title 16 of the United States Code, and restated them in Title 18 and a newly enacted Title 54. *See* Public Law 113–287 (Dec. 19, 2014). The amendment amends the Commentary to § 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources or Paleontological Resources; Unlawful Sale, Purchase, Exchange, Transportation, or Receipt of Cultural Heritage Resources or Paleontological Resources) to correct outdated references to certain sections in Title 16 that were restated, with minor revisions, when Congress enacted Title 54. It also deletes from the Commentary to § 2B1.5 the provision relating to the definition of ''historic resource,'' as that term was omitted from Title 54. In addition, the amendment makes a technical change to Appendix A (Statutory Index), to correct an outdated reference to 16 U.S.C. 413 by replacing it with the appropriate reference to 18 U.S.C. 1865(c).

Third, the amendment makes additional technical changes to reflect the editorial reclassification of certain sections in the United States Code. Effective September 1, 2017, the Office of Law Revision Counsel transferred certain provisions bearing on crime control and law enforcement, previously scattered throughout various parts of the United States Code, to a new Title 34. To reflect the new section numbers of the reclassified provisions, the amendment makes changes to: The Commentary to § 2A3.5 (Failure to Register as a Sex Offender); the Commentary to § 2X5.2 (Class A Misdemeanors (Not Covered by Another Specific Offense Guideline)); subsection (a)(10) of § 5B1.3 (Conditions of Probation); subsection (a)(8) of § 5D1.3 (Conditions of Supervised Release); and Appendix A (Statutory Index).

Fourth, the amendment makes clerical changes in §§ 2Q1.3 (Mishandling of Other Environmental Pollutants; Recordkeeping, Tampering, and Falsification), 2R1.1 (Bid-Rigging, Price-Fixing or Market-Allocation Agreements Among Competitors), 4A1.2 (Definitions and Instructions for Computing Criminal History), and 4B1.4 (Armed Career Criminal), to correct title references to § 4A1.3 (Departures Based on Inadequacy of Criminal History Category (Policy Statement)).

Finally, the amendment also makes clerical changes to—

- the Commentary to § 1B1.13 (Reduction in Term of Imprisonment Under 18 U.S.C. 3582(c)(1)(A) (Policy Statement)), by inserting a missing word in Application Note 4;
- subsection (d)(6) to § 2D1.11 (Unlawfully Distributing, Importing, Exporting or Possessing a Listed Chemical; Attempt or Conspiracy), by correcting a typographical error in the line referencing Pseudoephedrine;
- subsection (e)(2) to § 2D1.11 (Unlawfully Distributing, Importing, Exporting or Possessing a Listed Chemical; Attempt or Conspiracy), by correcting a punctuation mark under the heading relating to List I Chemicals;
- the Commentary to § 2M2.1 (Destruction of, or Production of Defective, War Material, Premises, or Utilities) captioned ''Statutory Provisions,'' by adding a missing section symbol and a reference to Appendix A (Statutory Index);
- the Commentary to § 2Q1.1 (Knowing Endangerment Resulting From Mishandling Hazardous or Toxic Substances, Pesticides or Other Pollutants) captioned ''Statutory Provisions,'' by adding a missing reference to 42 U.S.C. 7413(c)(5) and a reference to Appendix A (Statutory Index);
- the Commentary to § 2Q1.2 (Mishandling of Hazardous or Toxic Substances or Pesticides; Recordkeeping, Tampering, and Falsification; Unlawfully Transporting Hazardous Materials in Commerce) captioned ''Statutory Provisions,'' by adding a specific reference to 42 U.S.C. 7413(c)(1)–(4);
- the Commentary to § 2Q1.3 (Mishandling of Other Environmental Pollutants; Recordkeeping, Tampering, and Falsification) captioned ''Statutory Provisions,'' by adding a specific reference to 42 U.S.C. 7413(c)(1)–(4);
- subsection (a)(4) to § 5D1.3. (Conditions of Supervised Release), by changing an inaccurate reference to ''probation'' to ''supervised release'';
- subsection (a) of § 8C2.1 (Applicability of Fine Guidelines), by deleting an outdated reference to § 2C1.6, which was deleted by consolidation with § 2C1.2 (Offering, Giving, Soliciting, or Receiving a Gratuity) effective November 1, 2004; and
- the lines referencing ''18 U.S.C. 371'' and ''18 U.S.C. 1591'' in Appendix A (Statutory Index), by rearranging the order of certain Chapter Two guidelines references to place them in proper numerical order.

[FR Doc. 2018–09549 Filed 5–4–18; 8:45 am]

BILLING CODE 2210–40–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0232]

Agency Information Collection Activity: Application for Burial in a National Cemetery

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: National Cemetery Administration (NCA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 6, 2018.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Willie Lewis, National Cemetery Administration (43D3), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *willie.lewis@va.gov.* Please refer to ''OMB Control No. 2900–0232'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Willie Lewis at (202) 461–4242 or FAX (202) 501–2240.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, NCA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of NCA's functions, including whether the information will have practical utility; (2) the accuracy of NCA's estimate of the burden of the proposed collection of information; (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 through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Application for Burial in a National Cemetery.

OMB Control Number: 2900–0232.

Type of Review: Reinstatement, with change, of a previously approved collection.

Abstract: VA requires applicants for national cemetery burial to provide information to verify eligibility for burial in a national cemetery, to schedule interment and to provide services requested by the decedent's family or personal representative. This information is also used for planning and scheduling cemetery services and to provide for specific requests from family members or the personal representative.

Affected Public: Individuals and households.

Estimated Annual Burden: 33,750.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 135,000.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Department Clearance Officer, Office of Quality and Compliance, Department of Veterans Affairs.

[FR Doc. 2018–09564 Filed 5–4–18; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, 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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, and 495

[CMS–1694–P]

RIN 0938–AT27

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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

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 2019. Some of these proposed changes implement certain statutory provisions contained in the 21st Century Cures Act and the Bipartisan Budget Act of 2018, and other legislation. We also are proposing to make changes relating to Medicare graduate medical education (GME) affiliation agreements for new urban teaching hospitals. In addition, we are proposing to provide the market basket update that would 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 2019. 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 2019.

In addition, we are proposing to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs). We also are proposing to establish new requirements or revise existing requirements for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (now referred to as the Promoting Interoperability Programs). In addition, we are proposing changes to the requirements that apply to States operating Medicaid Promoting Interoperability Prrograms. We are proposing to update policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We also are proposing to make changes relating to the required supporting documentation for an acceptable Medicare cost report submission and the supporting information for physician certification and recertification of claims.

DATES: *Comment Period:* To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. on June 25, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1694–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 submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

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–1694–P, P.O. Box 8011, 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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1694–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, Sole Community Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786–4487, Mark Luxton, (410) 786–4530, and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Cindy Tourison, (410) 786–1093, Hospital Readmissions Reduction Program—Readmission Measures for Hospitals Issues.

James Poyer, (410) 786–2261, Hospital Readmissions Reduction Program—Administration Issues.

Elizabeth Bainger, (410) 786–0529, Hospital-Acquired Condition Reduction Program Issues.

Joseph Clift, (410) 786–4165, Hospital-Acquired Condition Reduction Program—Measures Issues.

Grace Snyder, (410) 786–0700 and James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Reena Duseja, (410) 786–1999 and Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Kim Spalding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Joel Andress, (410) 786–5237 and Caitlin Cromer, (410) 786–3106, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Elizabeth Holland, (410) 786-1309, Promoting Interoperability Programs Clinical Quality Measure Related Issues.

Kathleen Johnson, (410) 786–3295 and Steven Johnson (410) 786–3332, Promoting Interoperability Programs Nonclinical Quality Measure Related Issues.

Kellie Shannon, (410) 786–0416, Acceptable Medicare Cost Report Submissions Issues.

Thomas Kessler, (410) 786–1991, Physician Certification and Recertification of Claims.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

Electronic Access

This **Federal Register** document is available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at: *http://www.gpo.gov/fdsys*.

Tables Available Only Through the Internet on the CMS Website

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, the majority of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables generally will be available only through the Internet. The IPPS tables for this proposed rule are available through the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2019 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2019 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–1694–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 proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified above should contact Michael Treitel at (410) 786–4552.

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This 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.

We are proposing to establish new requirements and revise existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare. We also are proposing to establish new requirements and revise existing requirements for eligible professionals (EPs), eligible hospitals, and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs. We are proposing to update policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We also are proposing to make changes relating to the supporting documentation required for an acceptable Medicare cost report submission and the supporting information for physician certification and recertification of claims.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2019 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 (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, as added by section 3005 of the Affordable Care Act, which establishes 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, as added by section 3008 of the Affordable Care 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 added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act and 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'' under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare cohorts of hospitals to each other 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 (minus 0.2 percentage point for FY 2018 through FY 2019); 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(c) 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, and provides for a 4-year transitional blended payment rate for discharges occurring in LTCH cost reporting periods beginning in FYs 2016 through 2019. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B)(ii) by adding new clause (iv), which specifies that the IPPS comparable amount defined in subclause (I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1886(m)(6) of the Act, as amended by section 15009 of the 21st Century Cures Act (Pub. L. 114–255), which provides for a temporary exception to the application of the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals for discharges in cost reporting periods beginning during FYs 2018 and 2019.
- Section 1886(m)(6) of the Act, as amended by section 15010 of the 21st Century Cures Act (Pub. L. 114–255), which provides for a temporary exception to the application of the site neutral payment rate under the LTCH PPS for certain LTCHs with certain discharges with severe wounds occurring in cost reporting periods beginning during FY 2018.
- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206(c) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which provides for the establishment of a functional status quality measure in the LTCH QRP for change in mobility among inpatients requiring ventilator support.
- 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. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital

[1] Meaningful Measures webpage: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html*.

[2] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html*.

to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that will foster operational efficiencies and will reduce costs, including collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures; [3]
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in the following table:

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections
	Preventable Healthcare Harm
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals
	End of Life Care According to Preferences
	Patient's Experience of Care
	Patient Reported Functional Outcomes
Promote Effective Communication and Coordination of Care	Medication Management
	Admissions and Readmissions to Hospitals
	Transfer of Health Information and Interoperability
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care
	Management of Chronic Conditions
	Prevention, Treatment, and Management of Mental Health
	Prevention and Treatment of Opioid and Substance Use Disorders
	Risk Adjusted Mortality
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care
	Community Engagement
Make Care Affordable	Appropriate Use of Healthcare
	Patient-focused Episode of Care
	Risk Adjusted Total Cost of Care

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

3. Summary of the Major Provisions

Below we provide 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 included in this proposed rule is presented below in section I.D. of this preamble.

a. 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 2019, we are proposing to make an adjustment of +0.5 percent to the standardized amount.

b. Expansion of the Postacute Care Transfer Policy

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 by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, we are proposing to make conforming amendments to § 412.4(c) of the regulation, effective for discharges on or after October 1, 2018, to specify that 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 would be subject to payment as a transfer case.

c. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare

[3] Refer to section VIII.A.9.c.of the preamble of this proposed rule where we are seeking public comment on the potential future development and adoption of eCQMs.

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 are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2019. We are continuing 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. We also are continuing to incorporate data from Worksheet S–10 in the calculation of hospitals' share of the aggregate amount of uncompensated care by combining data on uncompensated care costs from Worksheet S–10 for FYs 2014 and 2015 with proxy data regarding a hospital's share of low-income insured days for FY 2013 to determine Factor 3 for FY 2019. In addition, we are proposing to use only data regarding low-income insured days for FY 2013 to determine the amount of uncompensated care payments for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers. For this proposed rule, we also are proposing the following policies: (1) For providers with multiple cost reports beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) in the rare case 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, the cost report that spans both fiscal years would be used for the latter fiscal year; and (3) to apply statistical trim methodologies to potentially aberrant cost-to-charge ratios (CCRs) and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

d. Proposed Changes to the LTCH PPS

In 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 2019. In addition, we are proposing to eliminate the 25-percent threshold policy, and under this proposal we would apply a one-time permanent adjustment of approximately −0.9 percent to the LTCH PPS standard Federal payment rate to ensure this proposed elimination of the 25-percent threshold policy is budget neutral.

e. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act and further 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 2018 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), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this proposed rule, we are proposing to establish the applicable periods for FY 2019, FY 2020, and FY 2021. We are also proposing to codify the definitions of dual-eligible patients, the proportion of dual-eligibles, and the applicable period for dual-eligibility.

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. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients, clinicians, and providers in our quality programs and the Patients Over Paperwork Initiative to reduce costs and burden and program complexity as discussed in section I.A.2. of the preamble of this proposed rule, we are proposing to remove a total of 10 measures from the Hospital VBP Program, all of which would continue to be used in the Hospital IQR Program or the HAC Reduction Program, in order to reduce the costs and complexity of tracking these measures in multiple programs. We also are proposing to adopt measure removal factors for the Hospital VBP Program. Specifically, we are proposing to remove six measures beginning with the FY 2021 program year: (1) Elective Delivery (NQF #0469) (PC–01); (2) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); (3) National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139); (4) American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753); (5) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia (MRSA) Outcome Measure (NQF #1716); and (6) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). We are also proposing to remove four measures from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule: (1) Patient Safety and Adverse Events (Composite) (NQF #0531) (PSI 90); (2) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment); (3) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and (4) Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (PN Payment) (NQF #2579). In addition, we are proposing to rename the Clinical Care domain as the Clinical Outcomes domain beginning with the FY 2020 program year; we are proposing to remove the Safety domain from the Hospital VBP Program, if our proposals to removal all of the measures in this domain are finalized, and to weight the three remaining domains as follows: Clinical Outcomes domain—50 percent; Person and Community Engagement domain—25 percent; and Efficiency and Cost Reduction domain—25 percent.

g. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care 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 a hospital whose ranking 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. As part of our agency-wide Patients over Paperwork and Meaningful Measures Initiatives, discussed in section I.A.2. of the preamble of this proposed rule, we are proposing that the measures currently included in the HAC Reduction Program should be retained because the measures address a performance gap in patient safety and reducing harm caused in the delivery of care. In this proposed rule, we are proposing to: (1) Establish administrative policies to collect, validate, and publicly report NHSN healthcare-associated infection (HAI) quality measure data that facilitate a seamless transition, independent of the Hospital IQR Program, beginning with January 1, 2019 infectious events; (2) change the scoring methodology by removing domains and assigning equal weighting to each measure for which a hospital has a measure; and (3) establish the applicable period for FY 2021. In addition, we are seeking stakeholder comment regarding the potential future inclusion of additional measures, including eCQMs.

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 proposed rule, we are proposing several changes. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients and clinicians in our quality programs and the Patients Over Paperwork initiative to reduce burden, cost, and program complexity as discussed in section I.A.2. of the preamble of this proposed rule, we are proposing to add a new measure removal factor and to remove a total of 39 measures from the Hospital IQR Program. For a full list of measures proposed for removal, we refer readers to section VIII.A.4.b. of the preamble of this proposed rule. Beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years, we are proposing to remove 17 claims-based measures and two structural measures. Beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years, we are proposing to remove eight chart-abstracted measures and two claims-based measures. Beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years, we are proposing to remove one chart-abstracted measure, one claims-based measure, and seven eCQMs from the Hospital IQR Program measure set. Beginning with the CY 2021 reporting period/FY 2023 payment determination, we are proposing to remove one claims-based measure.

In addition, for the CY 2019 reporting period/FY 2021 payment determination, we are proposing to: (1) Require the same eCQM reporting requirements that were adopted for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38355 through 38361), such that hospitals submit one, self-selected calendar quarter of 2019 discharge data for 4 eCQMs in the Hospital IQR Program measure set; and (2) require that hospitals use the 2015 Edition certification criteria for CEHRT. These proposals are in alignment with proposals or current established policies under the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). In addition, we are seeking public comment on two measures for potential future inclusion in the Hospital IQR Program, as well as the potential future development and adoption of electronic clinical quality measures generally.

i. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP is authorized by section 1886(m)(5) of the Act and applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary reduces 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 fails to submit data in accordance with the LTCH QRP requirements specified for that fiscal year. As part of agency-wide efforts under the Meaningful Measures Initiative to use a parsimonious set of the most meaningful measures for patients and clinicians in our quality programs and the Patients Over Paperwork Initiative to reduce cost and burden and program complexity as discussed in section I.A.2. of the preamble of this proposed rule, we are proposing to remove three measures from the LTCH QRP. We also are proposing to adopt a new measure removal factor and are proposing to codify the measure removal factors in our regulations. In addition, we are proposing to update our regulations to change methods by which an LTCH is notified of noncompliance with the requirements of the LTCH QRP for a program year; and how CMS will notify an LTCH of a reconsideration decision.

4. Summary of Costs and Benefits

- *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 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.) For FY 2019, we are proposing to make an adjustment of +0.5 percent to the standardized amount consistent with the MACRA.
- *Expansion of the Postacute Care Transfer Policy.* 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 by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, we are proposing to make conforming amendments to § 412.4(c) of the regulation to specify that, effective for discharges 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 would be subject to payment as a transfer case. We estimate that this statutory expansion to the postacute care transfer policy will reduce Medicare payments under the IPPS by approximately $240 million in FY 2019.
- *Proposed Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care.* Under section 1886(r) of the Act (as added by section 3133 of the Affordable Care Act), DSH payments to hospitals under section

1886(d)(5)(F) of the Act are reduced and an additional payment for uncompensated care is made to eligible hospitals beginning in FY 2014. Hospitals that receive Medicare DSH payments 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 remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, is the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2019, we are proposing to update our estimates of the three factors used to determine uncompensated care payments. We are continuing to use uninsured estimates produced by OACT as part of the development of the NHEA in the calculation of Factor 2. We also are continuing to incorporate data from Worksheet S–10 in the calculation of hospitals' share of the aggregate amount of uncompensated care by combining data on uncompensated care costs from Worksheet S–10 for FY 2014 and FY 2015 with proxy data regarding a hospital's share of low-income insured days for FY 2013 to determine Factor 3 for FY 2019. To determine the amount of uncompensated care for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and all-inclusive rate providers, we are proposing to use only the data regarding low-income insured days for FY 2013. In addition, in this proposed rule, we are proposing the following policies: (1) For providers with multiple cost reports beginning in the same fiscal year, to use the longest cost report and annualize Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (2) in the rare case 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, the cost report that spans both fiscal years would be used for the latter fiscal year; and (3) to apply statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs.

We are projecting that proposed estimated Medicare DSH payments, and additional payments for uncompensated care made for FY 2019, would increase payments overall by approximately 1.3 percent as compared to the estimate of overall payments, including Medicare DSH payments and uncompensated care payments that will be distributed in FY 2018. The additional payments have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated 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 409 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we are presenting in the preamble and Addendum of this proposed rule, which reflects the continuation of the transition of the statutory application of the site neutral payment rate, the update to the LTCH PPS standard Federal payment rate for FY 2019, and the proposed one-time permanent adjustment of approximately-0.9 percent to the LTCH PPS standard Federal payment rate to ensure this proposed elimination of the 25-percent threshold policy is budget neutral would result in an estimated decrease in payments in FY 2019 of approximately $5 million.
- *Proposed Changes to the Hospital Readmissions Reduction Program.* For FY 2019 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), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). Overall, in this proposed rule, we estimate that 2,610 hospitals would have their base operating DRG payments reduced by their determined proposed proxy FY 2019 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $566 million in FY 2019.
- *Value-Based Incentive Payments under the Hospital VBP Program.* We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2019 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 2019 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2019 discharges is approximately $1.9 billion.
- *Proposed 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. Any significant impact due to the proposed HAC Reduction Program changes for FY 2019, including which hospitals would receive the adjustment, would depend on actual experience.

The proposed removal of NHSN HAI measures from the Hospital IQR Program and the subsequent cessation of its validation processes for NHSN HAI measures and proposed creation of a validation process for the HAC Reduction program represent no net change in reporting burden across CMS hospital quality programs. However, if our proposal to remove HAI chart-abstracted measures from the Hospital IQR Program is finalized, we anticipate a total burden shift of 43,200 hours and approximately $1.6 million as a result of no longer needing to validate those HAI measures under the Hospital IQR Program and beginning the validation process under the HAC Reduction Program.

- *Proposed Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we estimate that our proposed requirements for the Hospital IQR Program would result in the following changes to costs and burdens related to information collection for this program compared to previously adopted requirements: (1) A total collection of information burden reduction of 1,046,071 hours and a total cost reduction of approximately $38.3 million for the CY 2019 reporting period/FY 2021 payment determination, due to the proposed removal of ED–1, IMM–2, and VTE–6 measures; and (2) a total collection of information burden reduction of 901,200 hours and a total cost reduction of $33 million for the CY 2020 reporting period/FY 2022 payment determination, due to: (a) The proposed removal of ED–2, and (b) validation of the NHSN HAI measures no longer being conducted under the Hospital IQR Program once the HAC Reduction Program begins validating these measures, as proposed in the preamble

of this proposed rule for the HAC Reduction Program.

Further, we anticipate that the proposed removal of 39 measures would result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs. We anticipate that our proposals will reduce the above-described costs.

• *Proposed Changes Related to the LTCH QRP.* In this proposed rule, we are proposing to remove three measures from the LTCH QRP, two measures beginning with the FY 2020 LTCH QRP and one measure beginning with the FY 2021 LTCH QRP. We also are proposing a new quality measure removal factor for the LTCH QRP. We estimate that the impact of these proposed changes is a reduction in costs of approximately $1,148 per LTCH annually or approximately $482,469 for all LTCHs annually.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (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 that considers the amount of uncompensated care beginning on October 1, 2013.

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. 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.

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 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. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. 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). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006 through September 30, 2016, all LTCHs were paid 100 percent of the Federal rate. 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, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, 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 (73 FR 26797 through 26798).

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 Proposed To Be Implemented in This Proposed Rule

1. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015 under the LTCH PPS will receive payment under a site neutral rate unless the discharge meets certain patient-specific criteria. In this proposed rule, we are continuing to update certain policies that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

2. 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, we are proposing to continue to implement portions of section 1899B of the Act, as added by section 2(a) of the IMPACT Act, which, in part, requires LTCHs, among other postacute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

3. 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.

4. The 21st Century Cures Act (Pub. L. 114–255)

The 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, contained the following provision affecting payments under the Hospital Readmissions Reduction Program,

which we are proposing to continue to implement in this proposed rule:

• Section 15002, which amended section 1886(q)(3) of the Act by adding subparagraphs (D) and (E), which requires the Secretary to develop a methodology for calculating the excess readmissions adjustment factor for the Hospital Readmissions Reduction Program based on cohorts defined by the percentage of dual-eligible patients (that is, patients who are eligible for both Medicare and full-benefit Medicaid coverage) cared for by a hospital. In this proposed rule, we are proposing to continue to implement changes to the payment adjustment factor to assess penalties based on a hospital's performance relative to other hospitals treating a similar proportion of dual-eligible patients.

5. The Bipartisan Budget Act of 2018 (Pub. L. 115–123)

The Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, contains provisions affecting payments under the IPPS and the LTCH PPS, which we are proposing to implement or continue to implement in this proposed rule:

• Section 50204 amended section 1886(d)(12) of the Act to provide for certain temporary changes to the low-volume hospital payment adjustment policy for FYs 2018 through 2022. For FY 2018, this provision extends the qualifying criteria and payment adjustment formula that applied for FYs 2011 through 2017. For FYs 2019 through 2022, this provision modifies the discharge criterion and payment adjustment formula. In FY 2023 and subsequent fiscal years, the qualifying criteria and payment adjustment revert to the requirements that were in effect for FYs 2005 through 2010.

• Section 50205 extends the MDH program through FY 2022. It also provides for an eligible hospital that is located in a State with no rural area to qualify for MDH status under an expanded definition if the hospital satisfies any of the statutory criteria at section 1886(d)(8)(E)(ii)(I), (II) (as of January 1, 2018), or (III) of the Act to be reclassified as rural.

• Section 51005(a) modified section 1886(m)(6) of the Act by extending the blended payment rate for site neutral payment rate LTCH discharges for cost reporting periods beginning in FY 2016 by an additional 2 years (FYs 2018 and 2019). In addition, section 51005(b) reduces the LTCH IPPS comparable per diem amount used in the site neutral payment rate for FYs 2018 through 2026 by 4.6 percent. In this proposed rule, we are proposing to make conforming changes to the existing regulations.

• Section 53109 modified section 1886(d)(5)(J) of the Act to require that, beginning in FY 2019, discharges to hospice care will also qualify as a postacute care transfer and be subject to payment adjustments.

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we are setting forth proposed payment and policy changes to the Medicare IPPS for FY 2019 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we are setting 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 2019.

Below is a general summary of the proposed changes included 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 2019.

• Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2019 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 2019 status of new technologies approved for add-on payments for FY 2018 and a presentation of our evaluation and analysis of the FY 2019 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).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing 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:

• The proposed FY 2019 wage index update using wage data from cost reporting periods beginning in FY 2015.

• Proposal regarding other wage-related costs in the wage index.

• Calculation of the proposed occupational mix adjustment for FY 2019 based on the 2016 Occupational Mix Survey.

• Analysis and implementation of the proposed FY 2019 occupational mix adjustment to the wage index for acute care hospitals.

• Proposed application of the rural floor and the frontier State floor and the proposed expiration of the imputed floor.

• Proposals to codify policies regarding multicampus hospitals.

• 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.

• The proposed adjustment to the wage index for acute care hospitals for FY 2019 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

• Determination of the labor-related share for the proposed FY 2019 wage index.

• Public comment solicitation on wage index disparities.

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 postacute care transfer policy and special payment policy and implementation of the statutory changes to the postacute care transfer policy.

• Proposed changes to the inpatient hospital update for FY 2019.

• Proposed changes related to the statutory changes to the low-volume hospital payment adjustment policy.

• Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.

• The statutorily required IME adjustment factor for FY 2019.

• Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.

• Proposed changes to the effective date of SCH and MDH classification status determinations.

• Proposed changes related to the extension of the MDH program.

• Proposed changes to the rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission

measures and the process for hospital review and correction of those rates for FY 2019.

- Proposed changes to the requirements and provision 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 2019.
- Proposed changes to Medicare GME affiliation agreements for new urban teaching hospitals.
- Discussion of and proposals relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2019.
- Proposed revisions of the hospital inpatient admission orders documentation requirements.

4. Proposed FY 2019 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 2019.

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 2019.
- Proposed changes to the regulations governing satellite facilities.
- Proposed changes to the regulations governing excluded units of hospitals.
- 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 the 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 2019.
- Proposed changes to the blended payment rate for site neutral payment rate cases.
- Proposed elimination of the 25-percent threshold policy.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the 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).
- Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).
- Proposed changes to requirements pertaining to the clinical quality measurement for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

8. Proposed Revision to the Supporting Documentation Requirements for an Acceptable Medicare Cost Report Submission

In section IX. of the preamble of this proposed rule, we set forth proposed revisions to the supporting documentation required for an acceptable Medicare cost report submission.

9. Requirements for Hospitals To Make Public List of Standard Charges

In section X. of the preamble of this proposed rule, we discuss our efforts to further improve the public accessibility of hospital standard charge information, effective January 1, 2019, in accordance with section 2718(e) of the Public Health Service Act.

10. Proposed Revisions Regarding Physician Certification and Recertification of Claims

In section XI. of the preamble of this proposed rule, we set forth proposed revisions to the requirements for supporting information used for physician certification and recertification of claims.

11. Request for Information

In section XII. of the preamble of this proposed rule, we include a request for information on possible establishment of CMS patient health and safety requirements for hospitals and other Medicare- and Medicaid-participating providers and suppliers for interoperable electronic health records and systems for electronic health care information exchange.

12. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In section V. of the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2019 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, we address the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2019 for certain hospitals excluded from the IPPS.

13. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2019 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 2019. We are proposing to establish the adjustments for wage levels, 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.

14. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, and PCHs.

15. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this 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 2019 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.

16. 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 2018 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 2018 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*.

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. 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. MS–DRG Reclassifications

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 2018 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; and 82 FR 38010 through 38085, respectively).

C. Adoption of the MS–DRGs in FY 2008

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).

D. Proposed FY 2019 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 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. Adjustment Made for FY 2018 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 to a 0.4588 percentage point. 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. This is a permanent adjustment to payment rates. While we did not address future adjustments required under section 414 of the MACRA and section 15005 of Public Law 114–255 at that time, we stated that we expected to propose positive 0.5 percentage point adjustments to the standardized amounts for FYs 2019 through 2023.

3. Proposed Adjustment for FY 2019

Consistent with the requirements of section 414 of the MACRA, we are proposing to implement a positive 0.5 percentage point adjustment to the standardized amount for FY 2019. This would be a permanent adjustment to payment rates. We plan to propose future adjustments required under section 414 of the MACRA for FYs 2020 through 2023 in future rulemaking.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

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 calculate the IPPS MS–DRG relative weights using 19 CCRs, which now include distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion of Policy for FY 2019

Consistent with our established policy, we are calculating the proposed MS–DRG relative weights for FY 2019 using two data sources: The MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the proposed 19 CCRs and the proposed MS–DRG relative weights for FY 2019 is included in section II.G. of the preamble to this FY 2019 IPPS/LTCH PPS proposed rule. As we did with the FY 2018 IPPS/LTCH PPS final rule, for this 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 2019 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

F. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2019 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 2019 MS–DRG Updates

CMS has previously encouraged input from our stakeholders concerning the annual IPPS updates when that input was made available to us by December 7 of the year prior to the next annual proposed rule update. As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), as we work with the public to examine the ICD–10 claims data used for updates to the ICD–10 MS DRGs, we would like to examine areas where the MS–DRGs can be improved, which will require additional time for us to review requests from the public to make specific updates, analyze claims data, and consider any proposed updates. Given the need for more time to carefully evaluate requests and propose updates, we changed the deadline to request updates to the MS–DRGs to November 1 of each year. This will provide an additional 5 weeks for the data analysis and review process. Interested parties had to submit any comments and suggestions for FY 2019 by November 1, 2017, and are encouraged to submit any comments and suggestions for FY 2020 by November 1, 2018 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov.* The comments that were submitted in a timely manner for FY 2019 are discussed in this section of the preamble of this proposed rule.

Following are the changes that we are proposing to the MS–DRGs for FY 2019 in this FY 2019 IPPS/LTCH PPS proposed rule. 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 2019 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2017 update of the FY 2017 MedPAR file, which contains hospital bills received through September 30, 2017, for discharges occurring through September 30, 2017. In our discussion of the proposed MS–DRG reclassification changes, we refer to our analysis of claims data from the ''September 2017 update of the FY 2017 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.

2. Pre-MDC

a. Heart Transplant or Implant of Heart Assist System

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), we stated our intent to review the ICD–10 logic for Pre-MDC MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively), as well as MS–DRG 215 (Other Heart Assist System Implant) and MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively) where procedures involving heart assist devices are currently assigned. We also encouraged the public to submit any comments on restructuring the MS–DRGs for heart assist system procedures to the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

The logic for Pre-MDC MS–DRGs 001 and 002 is comprised of two lists. The first list includes procedure codes identifying a heart transplant procedure, and the second list includes procedure codes identifying the implantation of a heart assist system. The list of procedure codes identifying the implantation of a heart assist system includes the following three codes.

ICD–10–PCS code	Code description
02HA0QZ	Insertion of implantable heart assist system into heart, open approach.
02HA3QZ	Insertion of implantable heart assist system into heart, percutaneous approach.
02HA4QZ	Insertion of implantable heart assist system into heart, percutaneous endoscopic approach.

In addition to these three procedure codes, there are also 33 pairs of code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 001 and 002. The code combinations are represented by two procedure codes and include either one code for the insertion of the device with one code for removal of the device or one code for the revision of the device with one code for the removal of the device. The 33 pairs of code combinations are listed below.

Code	Code description		Code	Code description
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA0RS	Insertion of biventricular short-term external heart assist system into heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA3RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.

Code	Code description		Code	Code description
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA0QZ	Revision of implantable heart assist system in heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA0QZ	Revision of implantable heart assist system in heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA0QZ	Revision of implantable heart assist system in heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA0RZ	Revision of short-term external heart assist system in heart, open approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA0RZ	Revision of short-term external heart assist system in heart, open approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA0RZ	Revision of short-term external heart assist system in heart, open approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA3RZ	Revision of short-term external heart assist system in heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA3RZ	Revision of short-term external heart assist system in heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA3RZ	Revision of short-term external heart assist system in heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA4QZ	Revision of implantable heart assist system in heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA4QZ	Revision of implantable heart assist system in heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA4QZ	Revision of implantable heart assist system in heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA4RZ	Revision of short-term external heart assist system in heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA4RZ	Revision of short-term external heart assist system in heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02WA4RZ	Revision of short-term external heart assist system in heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.

In response to our solicitation for public comments on restructuring the MS–DRGs for heart assist system procedures, commenters recommended that CMS maintain the current logic under the Pre-MDC MS–DRGs 001 and 002. Similar to the discussion in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38011 through 38012) involving MS–DRG 215 (Other Heart Assist System Implant), the commenters provided examples of common clinical scenarios involving a left ventricular assist device (LVAD) and included the procedure codes that were reported under the ICD–9 based MS–DRGs in comparison to the procedure codes reported under the ICD–10 MS–DRGs, which are reflected in the following table.

Procedure	ICD–9–CM procedure code	ICD–9 MS–DRG	ICD–10–PCS codes	ICD–10 MS–DRG
New LVAD inserted	37.66 (Insertion of implantable heart assist system).	001 or 002	02WA0QZ (Insertion of implantable heart assist system into heart, open approach). 02WA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach). 02WA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach).	001 or 002
LVAD Exchange—existing LVAD is removed and replaced with either new LVAD system or new LVAD pump.	37.63 (Repair of heart assist system).	215	02PA0QZ (Removal of implantable heart assist system from heart, open approach). 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach). 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach) and. 02WA0QZ (Insertion of implantable heart assist system into heart, open approach). 02WA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach). 02WA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach).	001 or 002
LVAD revision and repair—existing LVAD is adjusted or repaired without removing the existing LVAD device.	37.63 (Repair of heart assist system).	215	02WA0QZ (Revision of implantable heart assist system in heart, open approach). 02WA3QZ (Revision of implantable heart assist system in heart, percutaneous approach). 02WA4QZ (Revision of implantable heart assist system in heart, percutaneous endoscopic approach).	215

The commenters noted that, for Pre-MDC MS–DRGs 001 and 002, the procedures involving the insertion of an implantable heart assist system, such as the insertion of a LVAD, and the procedures involving exchange of an LVAD (where an existing LVAD is removed and replaced with either a new LVAD or a new LVAD pump) demonstrate clinical similarities and utilize similar resources. Although the commenters recommended that CMS maintain the current logic under the Pre-MDC MS–DRGs 001 and 002, they also recommended that CMS continue to monitor the data in these MS–DRGs for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of patients undergoing procedures utilizing heart assist devices. The commenters also requested that coding guidance be issued for assignment of the correct ICD–10–PCS procedure codes describing LVAD exchanges to encourage accurate reporting of these procedures.

We agree with the commenters that we should continue to monitor the data in Pre-MDC MS–DRGs 001 and 002 for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of patients undergoing procedures utilizing heart assist devices. In response to the request that coding guidance be issued for assignment of the correct ICD–10–PCS procedure codes describing LVAD exchanges to encourage accurate reporting of these procedures, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), coding advice is issued independently from payment policy. We also noted that, historically, we have not provided coding advice in rulemaking with respect to policy (82 FR 38045). We collaborate with the American Hospital Association (AHA) through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding. We recommend that the requestor and other interested parties submit any questions pertaining to correct coding for these technologies to the AHA.

In response to the public comments we received on this topic, we are providing the results of our claims analysis from the September 2017 update of the FY 2017 MedPAR file for cases in Pre-MDC MS–DRGs 001 and 002. Our findings are shown in the following table.

MS–DRGs FOR HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 001—All cases	1,993	35.6	$185,660
MS–DRG 002—All cases	179	18.3	99,635

As shown in this table, for MS–DRG 001, there were a total of 1,993 cases with an average length of stay of 35.6 days and average costs of $185,660. For MS–DRG 002, there were a total of 179 cases with an average length of stay of 18.3 days and average costs of $99,635.

We then examined claims data in Pre-MDC MS–DRGs 001 and 002 for cases that reported one of the three procedure codes identifying the implantation of a heart assist system such as the LVAD. Our findings are shown in the following table.

MS–DRGs FOR HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 001—All cases	1,993	35.6	$185,660
MS–DRG 001—Cases with procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach)	1,260	35.5	206,663
MS–DRG 001—Cases with procedure code 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach)	1	8	33,889
MS–DRG 001—Cases with procedure code 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 002—All cases	179	18.3	99,635
MS–DRG 002—Cases with procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach)	82	19.9	131,957
MS–DRG 002—Cases with procedure code 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach)	0	0	0
MS–DRG 002—Cases with procedure code 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach)	0	0	0

As shown in this table, for MS–DRG 001, there were a total of 1,260 cases reporting procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach) with an average length of stay of 35.5 days and average costs of $206,663. There was one case that reported procedure code 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach) with an average length of stay of 8 days and average costs of $33,889. There were no cases reporting procedure code 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach). For MS–DRG 002, there were a total of 82 cases reporting procedure code 02HA0QZ (Insertion of implantable heart assist system into heart, open approach) with an average length of stay of 19.9 days and average costs of $131,957. There were no cases reporting procedure codes 02HA3QZ (Insertion of implantable heart assist system into heart, percutaneous approach) or 02HA4QZ (Insertion of implantable heart assist system into heart, percutaneous endoscopic approach).

We also examined the cases in MS–DRGs 001 and 002 that reported one of the possible 33 pairs of code combinations or clusters. Our findings are shown in the following 8 tables. The first table provides the total number of cases reporting a procedure code combination (or cluster) compared to all of the cases in the respective MS–DRG, followed by additional detailed tables showing the number of cases, average length of stay, and average costs for each specific code combination that was reported in the claims data.

HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001 and 002	Number of cases	Average length of stay	Average costs
MS–DRG 001—All cases	1,993	35.6	$185,660
MS–DRG 001—Cases with a procedure code combination (cluster)	149	28.4	179,607
MS–DRG 002—All cases	179	18.3	99,635
MS–DRG 002—Cases with a procedure code combination (cluster)	6	3.8	57,343

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02HA0RS (Insertion of biventricular short-term external heart assist system into heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	3	20.3	$121,919
Cases with a procedure code combination of 02HA0RS (Insertion of biventricular short-term external heart assist system into heart, open approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	2	12	114,688
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	5	17	119,027

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

	Number of cases	Average length of stay	Average costs
MS–DRG 001			
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	30	55.6	$351,995
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	19	29.8	191,163
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	49	45.6	289,632
MS–DRG 002			
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	1	4	48,212
Cases with a procedure code combination of 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	2	4.5	66,386
All cases reporting one or more of the above procedure code combinations in MS–DRG 002	3	4.3	60,328
All cases reporting one or more of the above procedure code combinations across both MS–DRGs 001 and 002	52	43.3	276,403

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

	Number of cases	Average length of stay	Average costs
MS–DRG 001			
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	3	43.3	$233,330
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	24	14.8	113,955
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	1	44	153,284
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	28	18.9	128,150
MS–DRG 002			
Cases with a procedure code combination of 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	2	4	$30,954
All cases reporting one of the above procedure code combinations in MS–DRG 002	2	4	30,954
All cases reporting one or more of the above procedure code combinations across both MS-DRGs 001 and 002	30	17.9	121,670

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	4	17.3	$154,885
Cases with a procedure code combination of 02HA4RZ (Insertion of short-term external heart assist system into heart, open approach) *with* 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	2	15.5	80,852
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	6	16.7	130,207

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02WA0QZ (Revision of implantable heart assist system in heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	1	105	$516,557

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

MS–DRG 001	Number of cases	Average length of stay	Average costs
Cases with a procedure code combination of 02WA0RZ (Revision of short-term external heart assist system in heart, open approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	2	40	$285,818
Cases with a procedure code combination of 02WA0RZ (Revision of short-term external heart assist system in heart, open approach) *with* 02PA03Z (Removal of short-term external heart assist system from heart, percutaneous approach)	1	43	372,673
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	3	41	314,770

PROCEDURE CODE COMBINATIONS FOR IMPLANT OF HEART ASSIST SYSTEM

	Number of cases	Average length of stay	Average costs
MS–DRG 001			
Cases with a procedure code combination of 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	2	24	$123,084
Cases with a procedure code combination of 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	55	14.7	104,963
All cases reporting one or more of the above procedure code combinations in MS–DRG 001	57	15	105,599
MS–DRG 002			
Cases with a procedure code combination of 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach) *with* 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	1	2	101,168
All cases reporting one or more of the above procedure code combinations across both MS–DRGs 001 and 002	58	14.8	105,522
MS–DRG 001			
Cases with a procedure code combination of 02WA4RZ (Revision of short-term external heart assist system in heart, percutaneous endoscopic approach) *with* 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	1	10	112,698

We did not find any cases reporting the following procedure code combinations (clusters) in the claims data.

02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.
02HA4RS	Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA0RZ	Removal of short-term external heart assist system from heart, open approach.
02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA3RZ	Removal of short-term external heart assist system from heart, percutaneous approach.

02WA3QZ	Revision of implantable heart assist system in heart, percutaneous approach.	with	02PA4RZ	Removal of short-term external heart assist system from heart, percutaneous endoscopic approach.

The data show that there are differences in the average length of stay and average costs for cases in Pre-MDC MS–DRGs 001 and 002 according to the type of procedure (insertion, revision, or removal), the type of device (biventricular short-term external heart assist system, short-term external heart assist system or implantable heart assist system), and the approaches that were utilized (open, percutaneous, or percutaneous endoscopic). We agree with the commenters' recommendation to maintain the structure of Pre-MDC MS–DRGs 001 and 002 for FY 2019 and will continue to analyze the claims data. We are inviting public comments on our decision to maintain the current structure of Pre-MDC MS–DRGs 001 and 002 for FY 2019.

Commenters also suggested that CMS maintain the current logic for MS–DRG 215 (Other Heart Assist System Implant), but they recommended that CMS continue to monitor the data in MS–DRG 215 for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of procedures utilizing heart assist devices. We also received a request to review claims data for procedures involving extracorporeal membrane oxygenation (ECMO) in combination with the insertion of a percutaneous short-term external heart assist device to determine if the current MS–DRG assignment is appropriate.

The logic for MS–DRG 215 is comprised of the procedure codes shown in the following table, for which we examined claims data in the September 2017 update of the FY 2017 MedPAR file in response to the commenters' requests. Our findings are shown in the following table.

MS–DRG 215

[Other heart assist system implant]

	Number of cases	Average length of stay	Average costs
All cases	3,428	8.7	$68,965
Cases with procedure code 02HA0RJ (Insertion of short-term external heart assist system into heart, intraoperative, open approach)	0	0	0
Cases with procedure code 02HA0RS (Insertion of biventricular short-term external heart assist system into heart, open approach)	9	10	118,361
Cases with procedure code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach)	66	11.5	99,107
Cases with procedure code 02HA3RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach)	0	0	0
Cases with procedure code 02HA3RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous approach)	117	7.2	64,302
Cases with procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach)	3,136	8.4	67,670
Cases with procedure code 02HA4RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach)	0	0	0
Cases with procedure code 02HA4RS (Insertion of biventricular short-term external heart assist system into heart, percutaneous endoscopic approach)	1	2	43,988
Cases with procedure code 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach)	31	5.3	57,042
Cases with procedure code 02WA0JZ (Revision of synthetic substitute in heart, open approach)	1	84	366,089
Cases with procedure code 02WA0QZ (Revision of implantable heart assist system in heart, open approach)	56	25.1	123,410
Cases with procedure code 02WA0RS (Revision of biventricular short-term external heart assist system in heart, open approach)	0	0	0
Cases with procedure code 02WA0RZ (Revision of short-term external heart assist system in heart, open approach)	8	13.5	99,378
Cases with procedure code 02WA3QZ (Revision of implantable heart assist system in heart, percutaneous approach)	0	0	0
Cases with procedure code 02WA3RS (Revision of biventricular short-term external heart assist system in heart, percutaneous approach)	0	0	0
Cases with procedure code 02WA3RZ (Revision of short-term external heart assist system in heart, percutaneous approach)	80	10	71,077
Cases with procedure code 02WA4QZ (Revision of implantable heart assist system in heart, percutaneous endoscopic approach)	0	0	0
Cases with procedure code 02WA4RS (Revision of biventricular short-term external heart assist system in heart, percutaneous endoscopic approach)	0	0	0
Cases with procedure code 02WA4RZ (Revision of short-term external heart assist system in heart, percutaneous endoscopic approach)	0	0	0

As shown in this table, for MS–DRG 215, we found a total of 3,428 cases with an average length of stay of 8.7 days and average costs of $68,965. For procedure codes describing the insertion of a biventricular short-term external heart

assist system with open, percutaneous or percutaneous endoscopic approaches, we found a total of 127 cases with an average length of stay ranging from 2 to 10 days and average costs ranging from $43,988 to $118,361. For procedure codes describing the insertion of a short-term external heart assist system with open, percutaneous or percutaneous endoscopic approaches, we found a total of 3,233 cases with an average length of stay ranging from 5.3 days to 11.5 days and average costs ranging from $57,042 to $99,107. For procedure codes describing the revision of a short-term external heart assist system with open or percutaneous approaches, we found a total of 88 cases with an average length of stay ranging from 10 to 13.5 days and average costs ranging from $71,077 to $99,378. We found 1 case reporting procedure code 02WA0JZ (Revision of synthetic substitute in heart, open approach), with an average length of stay of 84 days and average costs of $366,089. Lastly, we found 56 cases reporting procedure code 02WA0QZ (Revision of implantable heart assist system in heart, open approach) with an average length of stay of 25.1 days and average costs of $123,410.

As the data show, there is a wide range in the average length of stay and the average costs for cases reporting procedures that involve a biventricular short-term external heart assist system versus a short-term external heart assist system. There is an even greater range in the average length of stay and the average costs when comparing the revision of a short-term external heart assist system to the revision of a synthetic substitute in the heart or to the revision an implantable heart assist system.

We agree with the commenters that continued monitoring of the data and further analysis is necessary prior to proposing any modifications to MS–DRG 215. As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), we are aware that the AHA published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices due to the technology being approved for new indications. The current claims data do not yet reflect that updated guidance. We also note that there have been recent updates to the descriptions of the codes for heart assist devices in the past year. For example, the qualifier ''intraoperative'' was added effective October 1, 2017 (FY 2018) to the procedure codes describing the insertion of short-term external heart assist system procedures to distinguish between procedures where the device was only used intraoperatively and was removed at the conclusion of the procedure versus procedures where the device was not removed at the conclusion of the procedure and for which that qualifier would not be reported. The current claims data do not yet reflect these new procedure codes, which are displayed in the following table and are assigned to MS–DRG 215.

ICD–10–PCS code	Code description
02HA0RJ	Insertion of short-term external heart assist system into heart, intraoperative, open approach.
02HA3RJ	Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach.
02HA4RJ	Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach.

Our clinical advisors agree that additional claims data are needed for analysis prior to proposing any changes to MS–DRG 215. Therefore, we are proposing not to make any modifications to MS–DRG 215 for FY 2019. We are inviting public comments on our proposal.

As stated earlier in this section, we also received a request to review cases reporting the use of ECMO in combination with the insertion of a percutaneous short-term external heart assist device. Under ICD–10–PCS, ECMO is identified with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) and the insertion of a percutaneous short-term external heart assist device is identified with procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach). According to the commenter, when ECMO procedures are performed percutaneously, they are less invasive and less expensive than traditional ECMO. The commenter also noted that, currently under ICD–10–PCS, there is not a specific procedure code to identify percutaneous ECMO, and providers are only able to report ICD–10–PCS procedure code 5A15223, which may be inappropriately resulting in a higher paying MS–DRG. Therefore, the commenter submitted a separate request to create a new ICD–10–PCS procedure code specifically for percutaneous ECMO which was discussed at the March 6–7, 2018 ICD–10 Coordination and Maintenance Committee Meeting. We refer readers to section II.F.18. of the preamble of this proposed rule for further information regarding this meeting and the discussion for a new procedure code.

The requestor suggested that cases reporting a procedure code for ECMO in combination with the insertion of a percutaneous short-term external heart assist device could be reassigned from Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure) to MS–DRG 215. Our analysis involved examining cases in Pre-MDC MS–DRG 003 in the September 2017 update of the FY 2017 MedPAR file for cases reporting ECMO with and without the insertion of a percutaneous short-term external heart assist device. Our findings are shown in the following table.

ECMO AND PERCUTANEOUS SHORT-TERM EXTERNAL HEART ASSIST DEVICE

Pre-MDC MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 003—All cases	14,383	29.5	$118,218
MS–DRG 003—Cases with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous)	1,786	19	119,340
MS–DRG 003—Cases with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) and 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach)	94	11.4	110,874

ECMO AND PERCUTANEOUS SHORT-TERM EXTERNAL HEART ASSIST DEVICE—Continued

Pre-MDC MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 003—Cases with procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) and 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach)	1	1	64,319

As shown in this table, we found a total of 14,383 cases with an average length of stay of 29.5 days and average costs of $118,218 in Pre-MDC MS–DRG 003. We found 1,786 cases reporting procedure code 5A15223 (Extracorporeal membrane oxygenation, continuous) with an average length of stay of 19 days and average costs of $119,340. We found 94 cases reporting procedure code 5A15223 and 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach) with an average length of stay of 11.4 days and average costs of $110,874. Lastly, we found 1 case reporting procedure code 5A15223 and 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach) with an average length of stay of 1 day and average costs of $64,319.

We also reviewed the cases in MS–DRG 215 for procedure codes 02HA3RZ and 02HA4RZ. Our findings are shown in the following table.

PERCUTANEOUS SHORT-TERM EXTERNAL HEART ASSIST DEVICE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 215—All cases	3,428	8.7	$68,965
MS–DRG 215—Cases with procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach)	3,136	8.4	67,670
MS–DRG 215—Cases with procedure code 02HA4RZ (Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach)	31	5.3	57,042

As shown in this table, we found a total of 3,428 cases with an average length of stay of 8.7 days and average costs of $68,965. We found a total of 3,136 cases reporting procedure code 02HA3RZ with an average length of stay of 8.4 days and average costs of $67,670. We found a total of 31 cases reporting procedure code 02HA4RZ with an average length of stay of 5.3 days and average costs of $57,042.

For Pre-MDC MS–DRG 003, while the average length of stay and average costs for cases where procedure code 5A15223 was reported with procedure code 02HA3RZ or procedure code 02HA4RZ are lower than the average length of stay and average costs for cases where procedure code 5A15223 was reported alone, we are unable to determine from the data if those ECMO procedures were performed percutaneously in the absence of a unique code. In addition, the one case reporting procedure code 5A15223 with 02HA4RZ only had a 1 day length of stay and it is unclear from the data what the circumstances of that case may have involved. For example, the patient may have been transferred or may have expired. Therefore, we are proposing to not reassign cases reporting procedure code 5A15223 when reported with procedure code 02HA3RZ or procedure code 02HA4RZ for FY 2019. Our clinical advisors agree that until there is a way to specifically identify percutaneous ECMO in the claims data to enable further analysis, a proposal at this time is not warranted. We are inviting public comments on our proposal.

A commenter also suggested that CMS maintain the current logic for MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively), but recommended that CMS continue to monitor the data in these MS–DRGs for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of procedures involving heart assist devices.

The logic for heart assist system devices in MS–DRGs 268 and 269 is comprised of the procedure codes shown in the following table, for which we examined claims data in the September 2017 update of the FY 2017 MedPAR file in response to the commenter's request. Our findings are shown in the following table.

MS–DRGS FOR AORTIC AND HEART ASSIST PROCEDURES EXCEPT PULSATION BALLOON

	Number of cases	Average length of stay	Average costs
MS–DRG 268—All cases	3,798	9.6	$49,122
MS–DRG 268—Cases with procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach)	16	23.4	79,850
MS–DRG 268—Cases with procedure code 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach)	28	10.5	31,797

MS–DRGs for Aortic and Heart Assist Procedures Except Pulsation Balloon—Continued

	Number of cases	Average length of stay	Average costs
MS–DRG 268—Cases with procedure code 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	96	12.4	51,469
MS–DRG 268—Cases with procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach)	5	7.8	37,592
MS–DRG 268—Cases with procedure code 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 268—Cases with procedure code 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 269—All cases	16,900	2.4	30,793
MS–DRG 269—Cases with procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach)	10	8	23,741
MS–DRG 269—Cases with procedure code 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA0RZ (Removal of short-term external heart assist system from heart, open approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach)	6	5	19,421
MS–DRG 269—Cases with procedure code 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach)	11	4	25,719
MS–DRG 269—Cases with procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach)	1	3	14,415
MS–DRG 269—Cases with procedure code 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0
MS–DRG 269—Cases with procedure code 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach)	0	0	0

As shown in this table, for MS–DRG 268, there were a total of 3,798 cases, with an average length of stay of 9.6 days and average costs of $49,122. There were 16 cases reporting procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach), with an average length of stay of 23.4 days and average costs of $79,850. There were no cases that reported procedure codes 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach), 02PA0RZ (Removal of short-term external heart assist system from heart, open approach), 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach), 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach) or 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach). There were 28 cases reporting procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach), with an average length of stay of 10.5 days and average costs of $31,797. There were 96 cases reporting procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach), with an average length of stay of 12.4 days and average costs of $51,469. There were 5 cases reporting procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach), with an average length of stay of 7.8 days and average costs of $37,592. For MS–DRG 269, there were a total of 16,900 cases, with an average length of stay of 2.4 days and average costs of $30,793. There were 10 cases reporting procedure code 02PA0QZ (Removal of implantable heart assist system from heart, open approach), with an average length of stay of 8 days and average costs of $23,741. There were no cases reporting procedure codes 02PA0RS (Removal of biventricular short-term external heart assist system from heart, open approach), 02PA0RZ (Removal of short-term external heart assist system from heart, open approach), 02PA3RS (Removal of biventricular short-term external heart assist system from heart, percutaneous approach), 02PA4RS (Removal of biventricular short-term external heart assist system from heart, percutaneous endoscopic approach) or 02PA4RZ (Removal of short-term external heart assist system from heart, percutaneous endoscopic approach). There were 6 cases reporting procedure code 02PA3QZ (Removal of implantable heart assist system from heart, percutaneous approach), with an average length of stay of 5 days and average costs of $19,421. There were 11 cases reporting procedure code 02PA3RZ (Removal of short-term external heart assist system from heart, percutaneous approach), with an average length of stay of 4 days and average costs of $25,719. There was 1 case reporting procedure code 02PA4QZ (Removal of implantable heart assist system from heart, percutaneous endoscopic approach), with an average length of stay of 3 days and average costs of $14,415.

The data show that there are differences in the average length of stay and average costs for cases in MS–DRGs 268 and 269 according to the type of device (short-term external heart assist system or implantable heart assist system), and the approaches that were utilized (open, percutaneous, or percutaneous endoscopic). We agree with the recommendation to maintain the structure of MS–DRGs 268 and 269 for FY 2019 and will continue to analyze the claims data for possible future updates. As such, we are proposing to not make any changes to the structure of MS–DRGs 268 and 269

for FY 2019. We are inviting public comments on our proposal.

b. Brachytherapy

We received a request to create a new Pre-MDC MS–DRG for all procedures involving the CivaSheet® technology, an implantable, planar brachytherapy source designed to enable delivery of radiation to the site of the cancer tumor excision or debulking, while protecting neighboring tissue. The requestor stated that physicians have used the CivaSheet® technology for a number of indications, such as colorectal, gynecological, head and neck, soft tissue sarcomas and pancreatic cancer. The requestor noted that potential uses also include nonsmall-cell lung cancer, ocular melanoma, and atypical meningioma. Currently, procedures involving the CivaSheet® technology are reported using ICD–10–PCS Section D—Radiation Therapy codes, with the root operation ''Brachytherapy.'' These codes are non-O.R. codes and group to the MS–DRG to which the principal diagnosis is assigned.

In response to this request, we have analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for cases representing patients who received treatment that reported low dose rate (LDR) brachytherapy procedure codes across all MS–DRGs. We refer readers to Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes 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.html.* A detailed list of these procedure codes are shown in Table 6P.1. Our findings are reflected in the following table.

CASES REPORTING LOW DOSE RATE (LDR) BRACHYTHERAPY PROCEDURE CODES ACROSS ALL MS–DRGS

ICD–10–PCS procedures	Number of cases	Average length of stay	Average costs
MS–DRG 129 (Major Head and Neck Procedures with CC/MCC or Major Device)—Cases with procedure code D710BBZ (Low dose rate (LDR) brachytherapy of bone marrow using Palladium-103 (Pd-103))	1	7	$10,357
MS–DRG 724 (Malignancy, Male Reproductive System without CC/MCC)—Cases with procedure code DV10BBZ (Low dose rate (LDR) brachytherapy of prostate using Palladium-103 (Pd-103))	1	7	32,298
MS–DRG 129—Cases with procedure code DW11BBZ (Low dose rate (LDR) brachytherapy of head and neck using Palladium-103 (Pd-103))	1	3	42,565
MS–DRG 330 (Major Small and Large Bowel Procedures with CC)—Cases with procedure code DW16BBZ (Low dose rate (LDR) brachytherapy of pelvic region using Palladium-103 (Pd-103))	1	8	74,190

As shown in the immediately preceding table, we identified 4 cases reporting one of these LDR brachytherapy procedure codes across all MS–DRGs, with an average length of stay of 6.3 days and average costs of $39,853. We believe that creating a new Pre-MDC MS–DRG based on such a small number of cases could lead to distortion in the relative payment weights for the Pre-MDC MS–DRG. Having a larger number of clinically cohesive cases within the Pre-MDC MS–DRG provides greater stability for annual updates to the relative payment weights. Therefore, we are not proposing to create a new Pre-MDC MS–DRG for procedures involving the CivaSheet® technology for FY 2019. We are inviting public comments on our proposal to maintain the current MS-DRG structure for procedures involving the CivaSheet® technology.

c. Laryngectomy

The logic for case assignment to Pre-MDC MS–DRGs 11, 12, and 13 (Tracheostomy for Face, Mouth and Neck Diagnoses with MCC, with CC, and without CC/MCC, respectively) as displayed in the ICD–10 MS–DRG Version 35 Definitions Manual, which is available via the Internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending,* is comprised of a list of procedure codes for laryngectomies, a list of procedure codes for tracheostomies, and a list of diagnosis codes for conditions involving the face, mouth, and neck. The procedure codes for laryngectomies are listed separately and are reported differently from the procedure codes listed for tracheostomies. The procedure codes listed for tracheostomies must be reported with a diagnosis code involving the face, mouth, or neck as a principal diagnosis to satisfy the logic for assignment to Pre-MDC MS–DRG 11, 12, or 13. Alternatively, any principal diagnosis code reported with a procedure code from the list of procedure codes for laryngectomies will satisfy the logic for assignment to Pre-MDC MS–DRG 11, 12, or 13.

To improve the manner in which the logic for assignment is displayed in the ICD–10 MS–DRG Definitions Manual and to clarify how it is applied for grouping purposes, we are proposing to reorder the lists of the diagnosis and procedure codes. The list of principal diagnosis codes for face, mouth, and neck would be sequenced first, followed by the list of the tracheostomy procedure codes and, lastly, the list of laryngectomy procedure codes.

We also are proposing to revise the titles of Pre-MDC MS–DRGs 11, 12, and 13 from ''Tracheostomy for Face, Mouth and Neck Diagnoses with MCC, with CC and without CC/MCC, respectively'' to ''Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with MCC'', ''Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with CC'', and ''Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy without CC/MCC'', respectively, to reflect that laryngectomy procedures may also be assigned to these MS–DRGs.

We are inviting public comments on our proposals.

d. Chimeric Antigen Receptor (CAR) T-Cell Therapy

Chimeric Antigen Receptor (CAR) T-cell therapy is a cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and used to assist in the patient's treatment to attack certain cancerous cells. Blood is drawn from the patient and the T-cells are separated. The laboratory then utilizes the CAR process to genetically engineer the T-cells,

resulting in the addition of a chimeric antigen receptor that will bind to a certain protein on the patient's cancerous cells. The CAR T-cells are then administered to the patient by infusion.

Two CAR T-cell therapy drugs received FDA approval in 2017. KYMRIAH™ (manufactured by Novartis Pharmaceuticals Corporation) was approved for the use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. YESCARTA™ (manufactured by Kite Pharma, Inc.) was approved for use in the treatment of adult patients with relapsed or refractory large B-cell lymphoma and who have not responded to or who have relapsed after at least two other kinds of treatment.

Procedures involving the CAR T-cell therapy drugs are currently 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 both became effective October 1, 2017. Procedures described by these two ICD–10–PCS procedure codes are designated as non-O.R. procedures that have no impact on MS–DRG assignment.

We have received many inquiries from the public regarding payment of CAR T-cell therapy under the IPPS. Suggestions for the MS–DRG assignment for FY 2019 ranged from assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to an existing MS–DRG to the creation of a new MS–DRG for CAR T-cell therapy. In the context of the recommendation to create a new MS–DRG for FY 2019, we also received suggestions that payment should be established in a way that promotes comparability between the inpatient setting and outpatient setting.

As part of our review of these suggestions, we examined the existing MS–DRGs to identify the MS–DRGs that represent cases most clinically similar to those cases in which the CAR T-cell therapy procedures would be reported. The CAR T-cell procedures involve a type of autologous immunotherapy in which the patient's cells are genetically transformed and then returned to that patient after the patient undergoes cell depleting chemotherapy. Our clinical advisors believe that patients receiving treatment utilizing CAR T-cell therapy procedures would have similar clinical characteristics and comorbidities to those seen in cases representing patients receiving treatment for other hematopoietic carcinomas who are treated with autologous bone marrow transplant therapy that are currently assigned to MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). Therefore, after consideration of the inquiries received as to how the IPPS can appropriately group cases reporting the use of CAR T-cell therapy, we are proposing to assign ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 for FY 2019. In addition, we are proposing to revise the title of MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC'' to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy.''

However, we note that, as discussed in greater detail in section II.H.5.a. of the preamble of this proposed rule, the manufacturer of KYMRIAH™ and the manufacturer of YESCARTA™ submitted applications for new technology add-on payments for FY 2019. We also recognize that many members of the public have noted that the combination of the new technology add-on payment applications, the extremely high-cost of these CAR T-cell therapy drugs, and the potential for volume increases over time present unique challenges with respect to the MS–DRG assignment for procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy. We believe that, in the context of these pending new technology add-on payment applications, there may also be merit in the alternative suggestion we received to create a new MS–DRG for procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy to which we could assign ICD–10–PCS procedure codes XW033C3 and XW043C3, effective for discharges occurring in FY 2019. As noted in section II.H.5.a. of the preamble of this proposed rule, 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.

We are inviting public comments on our proposed approach of assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 for FY 2019. We also are inviting public comments on alternative approaches, including in the context of the pending KYMRIAH™ and YESCARTA™ new technology add-on payment applications, and the most appropriate way to establish payment for FY 2019 under any alternative approaches. Such payment alternatives may include using a CCR of 1.0 for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3, given that many public inquirers believed that hospitals would be unlikely to set charges different from the costs for KYMRIAH™ and YESCARTA™ CAR T-cell therapy drugs, as discussed further in section II.A.4.g.2. of the Addendum of this proposed rule. These payment alternatives, including payment under any potential new MS–DRG, also could take into account an appropriate portion of the average sales price (ASP) for these drugs, including in the context of the pending new technology add-on payment applications.

We are inviting comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices, which is a high priority for this Administration. In addition, we are considering approaches and authorities to encourage value-based care and lower drug prices. We solicit comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches.

As stated in section II.F.1.b. of the preamble of this proposed rule, we described the criteria used to establish new MS–DRGs. In particular, 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 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 decide whether patients are clinically distinct or similar to other patients 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 whether observed average differences are consistent across patients or attributable to cases that were 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. Based on the principles typically used to establish a new MS–DRG, we are soliciting comments on how the administration of the CAR T-cell

therapy drugs and associated services meet the criteria for the creation of a new MS–DRG. Also, 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. Given that a new MS–DRG must be established in a budget neutral manner, we are concerned with the redistributive effects away from core hospital services over time toward specialized hospitals and how that may affect payment for these core services. Therefore, we are soliciting public comments on our concerns with the payment alternatives that we are considering for CAR T-cell therapy drugs and therapies.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Epilepsy With Neurostimulator

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019), based on a request we received and our review of the claims data, the advice of our clinical advisors, and consideration of public comments, we finalized our proposal to reassign all cases reporting a principal diagnosis of epilepsy and one of the following ICD–10–PCS code combinations, which capture cases involving neurostimulator generators inserted into the skull (including cases involving the use of the RNS© neurostimulator), to retitled 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), 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); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

The finalized listing of epilepsy diagnosis codes (82 FR 38018 through 38019) contained codes provided by the requestor (82 FR 38016), in addition to diagnosis codes organized in subcategories G40.A– and G40.B– as recommended by a commenter in response to the proposed rule (82 FR 38018) because the diagnosis codes organized in these subcategories also are representative of diagnoses of epilepsy.

For FY 2019, we received a request to include two additional diagnosis codes organized in subcategory G40.1– in the listing of epilepsy diagnosis codes for cases assigned to MS–DRG 023 because these diagnosis codes also represent diagnoses of epilepsy. The two additional codes identified by the requestor are:

- G40.109 (Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus); and
- G40.111 (Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus).

We agree with the requestor that diagnosis codes G40.109 and G40.111 also are representative of epilepsy diagnoses and should be added to the listing of epilepsy diagnosis codes for cases assigned to MS–DRG 023 because they also capture a type of epilepsy. Our clinical advisors reviewed this issue and agree that adding the two additional epilepsy diagnosis codes is appropriate. Therefore, we are proposing to add ICD–10–CM diagnosis codes G40.109 and G40.111 to the listing of epilepsy diagnosis codes for cases assigned to MS–DRG 023, effective October 1, 2018.

We are inviting public comments on our proposal.

b. Neurological Conditions With Mechanical Ventilation

We received two separate, but related requests to create new MS–DRGs for cases that identify patients who have been diagnosed with neurological conditions classified under MDC 1 (Diseases and Disorders of the Nervous System) and who require mechanical ventilation with and without a thrombolytic and in the absence of an O.R. procedure. The requestors suggested that CMS consider when mechanical ventilation is reported with a neurological condition for the ICD–10 MS–DRG GROUPER assignment logic, similar to the current logic for MS–DRGs 207 and 208 (Respiratory System Diagnosis with Ventilator Support >96 Hours and <=96 Hours, respectively) under MDC 4 (Diseases and Disorders of the Respiratory System), which consider respiratory conditions that require mechanical ventilation and are assigned a higher relative weight.

The requestors stated that patients with a principal diagnosis of respiratory failure requiring mechanical ventilation are currently assigned to MS–DRG 207 (Respiratory System Diagnoses with Ventilator Support >96 Hours), which has a relative weight of 5.4845, and to MS–DRG 208 (Respiratory System Diagnoses with Ventilator Support <=96 Hours), which has a relative weight of 2.3678. The requestors also stated that patients with a principal diagnosis of ischemic cerebral infarction who received a thrombolytic agent during the hospital stay and did not undergo an O.R. procedure are assigned to MS–DRGs 061, 062, and 063 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) under MDC 1, while patients with a principal diagnosis of intracranial hemorrhage or ischemic cerebral infarction who did not receive a thrombolytic agent during the hospital stay and did not undergo an O.R. procedure are assigned to MS–DRGs 064, 065 and 66 (Intracranial Hemorrhage or Cerebral Infarction with MCC, with CC or TPA in 24 Hours, and without CC/MCC, respectively) under MDC 1.

The requestors provided the current FY 2018 relative weights for these MS–DRGs as shown in the following table.

MS–DRG	MS–DRG title	Relative weight
MS–DRG 061	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC	2.7979
MS–DRG 062	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with CC	l.9321
MS–DRG 063	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent without CC/MCC ..	l.6169
MS–DRG 064	Intracranial Hemorrhage or Cerebral Infarction with MCC	l.7685
MS–DRG 065	Intracranial Hemorrhage or Cerebral Infarction with CC or TPA in 24 hours	1.0311
MS–DRG 066	Intracranial Hemorrhage or Cerebral Infarction with MCC	.7466

The requestors stated that although the ICD–10–CM Official Guidelines for Coding and Reporting allow sequencing of acute respiratory failure as the principal diagnosis when it is jointly responsible (with an acute neurologic event) for admission, which would result in assignment to MS–DRGs 207 or 208 when the patient requires mechanical ventilation, it would not be appropriate to sequence acute respiratory failure as the principal diagnosis when it is secondary to intracranial hemorrhage or ischemic cerebral infarction.

The requestors also stated that reporting for other purposes, such as quality measures, clinical trials, and Joint Commission and State certification or survey cases, is based on the principal diagnosis, and it is important, from a quality of care perspective, that the intracranial hemorrhage or cerebral infarction codes continue to be sequenced as principal diagnosis. The requestors believed that cases of patients who present with cerebral infarction or cerebral hemorrhage and acute respiratory failure are currently in conflict for principal diagnosis sequencing because the cerebral infarction or cerebral hemorrhage code is needed as the principal diagnosis for quality reporting and other purposes. However, acute respiratory failure is needed as the principal diagnosis for purposes of appropriate payment under the MS–DRGs.

The requestors stated that by creating new MS–DRGs for neurological conditions with mechanical ventilation, those patients who require mechanical ventilation for airway protection on admission and those patients who develop acute respiratory failure requiring mechanical ventilation after admission can be grouped to MS–DRGs that provide appropriate payment for the mechanical ventilation resources. The requestors suggested two new MS–DRGs, citing as support that new MS–DRGs were created for patients with sepsis requiring mechanical ventilation greater than and less than 96 hours.

As discussed earlier in this section, the requests we received were separate, but related requests. The first request was to specifically identify patients presenting with intracranial hemorrhage or cerebral infarction with mechanical ventilation and create two new MS–DRGs as follows:

- Suggested new MS–DRG XXX (Intracranial Hemorrhage or Cerebral Infarction with Mechanical Ventilation >96 Hours); and
- Suggested new MS–DRG XXX (Intracranial Hemorrhage or Cerebral Infarction with Mechanical Ventilation <=96 Hours).

The second request was to consider *any* principal diagnosis under the current GROUPER logic for MDC 1 with mechanical ventilation and create two new MS–DRGs as follows:

- Suggested New MS–DRG XXX (Neurological System Diagnosis with Mechanical Ventilation 96+ Hours); and
- Suggested New MS–DRG XXX (Neurological System Diagnosis with Mechanical Ventilation ≤96 Hours).

Both requesters suggested that CMS use the three ICD–10–PCS codes identifying mechanical ventilation to assign cases to the respective suggested new MS–DRGs. The three ICD–10–PCS codes are shown in the following table.

ICD–10–PCS code	Code description
5A1935Z	Respiratory ventilation, less than 96 consecutive hours.
5A1945Z	Respiratory ventilation, 24–96 consecutive hours.
5A1955Z	Respiratory ventilation, greater than 96 consecutive hours.

Below we discuss the different aspects of each request in more detail.

The first request involved two aspects: (1) Analyzing patients diagnosed with cerebral infarction and required mechanical ventilation who received a thrombolytic (for example, TPA) and did not undergo an O.R. procedure; and (2) analyzing patients diagnosed with intracranial hemorrhage or ischemic cerebral infarction and required mechanical ventilation who did not receive a thrombolytic (for example, TPA) during the current episode of care and did not undergo an O.R. procedure.

For the first subset of patients, we analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 061, 062, and 063 because cases that are assigned to these MS–DRGs specifically identify patients who were diagnosed with a cerebral infarction and received a thrombolytic. The 90 ICD–10–CM diagnosis codes that specify a cerebral infarction and were included in our analysis are listed in Table 6P.1a associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html).*

The ICD–10–PCS procedure codes displayed in the following table describe use of a thrombolytic agent.

ICD–10–PCS code	Code description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach.
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach.
3E04017	Introduction of other thrombolytic into central vein, open approach.
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach.
3E05017	Introduction of other thrombolytic into peripheral artery, open approach.
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach.
3E06017	Introduction of other thrombolytic into central artery, open approach.
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach.
3E08017	Introduction of other thrombolytic into heart, open approach.
3E08317	Introduction of other thrombolytic into heart, percutaneous approach.

We examined claims data in MS–DRGs 061, 062, and 063 and identified cases that reported mechanical ventilation of any duration with a principal diagnosis of cerebral infarction where a thrombolytic agent was administered and the patient did not undergo an O.R. procedure. Our

findings are shown in the following table.

CEREBRAL INFARCTION WITH THROMBOLYTIC AND MV

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 061—All cases	5,192	6.4	$20,097
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	166	12.8	41,691
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation =24–96 hours	378	7.5	26,368
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <24 hours	214	4.9	19,795
MS–DRG 062—All cases	9,730	3.9	13,865
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation =24–96 hours	10	5.3	19,817
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <24 hours	23	3.8	14,026
MS–DRG 063—All cases	1,984	2.7	11,771
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation =24–96 hours	3	2.7	14,588
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <24 hours	5	2.0	11,195

As shown in this table, there were a total of 5,192 cases in MS–DRG 061 with an average length of stay of 6.4 days and average costs of $20,097. There were a total of 758 cases reporting the use of mechanical ventilation in MS–DRG 061 with an average length of stay ranging from 4.9 days to 12.8 days and average costs ranging from $19,795 to $41,691. For MS–DRG 062, there were a total of 9,730 cases with an average length of stay of 3.9 days and average costs of $13,865. There were a total of 33 cases reporting the use of mechanical ventilation in MS–DRG 062 with an average length of stay ranging from 3.8 days to 5.3 days and average costs ranging from $14,026 to $19,817. For MS-DRG 063, there were a total of 1,984 cases with an average length of stay of 2.7 days and average costs of $11,771. There were a total of 8 cases reporting the use of mechanical ventilation in MS–DRG 063 with an average length of stay ranging from 2.0 days to 2.7 days and average costs ranging from $11,195 to $14,588.

We then compared the total number of cases in MS–DRGs 061, 062, and 063 specifically reporting mechanical ventilation >96 hours with a principal diagnosis of cerebral infarction where a thrombolytic agent was administered and the patient did not undergo an O.R. procedure against the total number of cases reporting mechanical ventilation <=96 hours with a principal diagnosis of cerebral infarction where a thrombolytic agent was administered and the patient did not undergo an O.R. procedure. Our findings are shown in the following table.

CEREBRAL INFARCTION WITH THROMBOLYTIC AND MV

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 061—All cases	5,192	6.4	$20,097
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	166	12.8	41,691
MS–DRG 061—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <=96 hours	594	6.5	23,780
MS–DRG 062—All cases	9,730	3.9	13,865
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	0
MS–DRG 062—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <=96 hours	34	4.2	15,558
MS–DRG 063—All cases	1,984	2.7	11,771
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation >96 hours	0	0.0	$0
MS–DRG 063—Cases with principal diagnosis of cerebral infarction and mechanical ventilation <=96 hours	8	2.3	12,467

As shown in this table, the total number of cases reported in MS–DRG 061 was 5,192, with an average length of stay of 6.4 days and average costs of $20,097. There were 166 cases that reported mechanical ventilation >96

hours, with an average length of stay of 12.8 days and average costs of $41,691. There were 594 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 6.5 days and average costs of $23,780.

The total number of cases reported in MS–DRG 062 was 9,730, with an average length of stay of 3.9 days and average costs of $13,865. There were no cases identified in MS–DRG 062 where mechanical ventilation >96 hours was reported. However, there were 34 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 4.2 days and average costs of $15,558.

The total number of cases reported in MS–DRG 63 was 1,984 with an average length of stay of 2.7 days and average costs of $11,771. There were no cases identified in MS–DRG 063 where mechanical ventilation >96 hours was reported. However, there were 8 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 2.3 days and average costs of $12,467.

For the second subset of patients, we examined claims data for MS–DRGs 064, 065, and 066. We identified cases reporting mechanical ventilation of any duration with a principal diagnosis of cerebral infarction or intracranial hemorrhage where a thrombolytic agent was not administered during the current hospital stay and the patient did not undergo an O.R. procedure. The 33 ICD–10–CM diagnosis codes that specify an intracranial hemorrhage and were included in our analysis are listed in Table 6P.1b associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html).*

We also used the list of 90 ICD–10–CM diagnosis codes that specify a cerebral infarction listed in Table 6P.1a associated with this proposed rule for our analysis. We note that the GROUPER logic for case assignment to MS–DRG 065 includes that a thrombolytic agent (for example, TPA) was administered within 24 hours of the current hospital stay. The ICD–10–CM diagnosis code that describes this scenario is Z92.82 (Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility). We did not review the cases reporting that diagnosis code for our analysis. Our findings are shown in the following table.

CEREBRAL INFARCTION OR INTRACRANIAL HEMORRHAGE WITH MV AND WITHOUT THROMBOLYTIC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 064—All cases	76,513	6.0	$12,574
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	2,153	13.4	38,262
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation =24–96 hours	4,843	6.6	18,119
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <24 hours	4,001	3.1	8,675
MS–DRG 065—All cases	106,554	3.7	7,236
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	22	10.2	20,759
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation =24–96 hours	127	4.2	12,688
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <24 hours	301	2.1	6,145
MS–DRG 066—All cases	34,689	2.5	5,321
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	1	4.0	3,426
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation =24–96 hours	31	3.7	10,364
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <24 hours	163	1.4	4,148

The total number of cases reported in MS–DRG 064 was 76,513, with an average length of stay of 6.0 days and average costs of $12,574. There were a total of 10,997 cases reporting the use of mechanical ventilation in MS–DRG 064 with an average length of stay ranging from 3.1 days to 13.4 days and average costs ranging from $8,675 to $38,262. For MS–DRG 065, there were a total of 106,554 cases with an average length of stay of 3.7 days and average costs of $7,236. There were a total of 450 cases reporting the use of mechanical ventilation in MS–DRG 065 with an average length of stay ranging from 2.1 days to 10.2 days and average costs ranging from $6,145 to $20,759. For MS–DRG 066, there were a total of 34,689 cases with an average length of stay of 2.5 days and average costs of $5,321. There were a total of 195 cases reporting the use of mechanical ventilation in MS–DRG 066 with an average length of stay ranging from 1.4 days to 4.0 days and average costs ranging from $3,426 to $10,364.

We then compared the total number of cases in MS–DRGs 064, 065, and 066 specifically reporting mechanical ventilation >96 hours with a principal diagnosis of cerebral infarction or intracranial hemorrhage where a thrombolytic agent was not administered and the patient did not undergo an O.R. procedure against the total number of cases reporting mechanical ventilation <=96 hours with a principal diagnosis of cerebral infarction or intracranial hemorrhage where a thrombolytic agent was not administered and the patient did not undergo an O.R. procedure. Our findings are shown in the following table.

CEREBRAL INFARCTION OR INTRACRANIAL HEMORRHAGE WITH MV AND WITHOUT THROMBOLYTIC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 064—All cases	76,513	6.0	$12,574
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	2,153	13.4	38,262
MS–DRG 064—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <=96 hours	8,794	4.9	13,704
MS–DRG 065—All cases	106,554	3.7	7,236
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	22	10.2	20,759
MS–DRG 065—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <=96 hours	428	2.7	8,086
MS–DRG 066—All cases	34,689	2.5	5,321
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation >96 hours	1	4.0	3,426
MS–DRG 066—Cases with principal diagnosis of cerebral infarction or intracranial hemorrhage and mechanical ventilation <=96 hours	194	1.8	5,141

The total number of cases reported in MS–DRG 064 was 76,513, with an average length of stay of 6.0 days and average costs of $12,574. There were 2,153 cases that reported mechanical ventilation >96 hours, with an average length of stay of 13.4 days and average costs of $38,262, and there were 8,794 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 4.9 days and average costs of $13,704.

The total number of cases reported in MS–DRG 65 was 106,554, with an average length of stay of 3.7 days and average costs of $7,236. There were 22 cases that reported mechanical ventilation >96 hours, with an average length of stay of 10.2 days and average costs of $20,759, and there were 428 cases that reported mechanical ventilation<=96 hours, with an average length of stay of 2.7 days and average costs of $8,086.

The total number of cases reported in MS–DRG 66 was 34,689, with an average length of stay of 2.5 days and average costs of $5,321. There was one case that reported mechanical ventilation >96 hours, with an average length of stay of 4.0 days and average costs of $3,426, and there were 194 cases that reported mechanical ventilation <=96 hours, with an average length of stay of 1.8 days and average costs of $5,141.

We also analyzed claims data for MS–DRGs 207 and 208. As shown in the following table, there were a total of 19,471cases found in MS–DRG 207 with an average length of stay of 13.8 days and average costs of $38,124. For MS–DRG 208, there were a total of 55,802 cases found with an average length of stay of 6.7 days and average costs of $17,439.

RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 207—All cases	19,471	13.8	$38,124
MS–DRG 208—All cases	55,802	6.7	17,439

Our analysis of claims data relating to the first request for MS–DRGs 061, 062, 063, 064, 065, and 066 and consultation with our clinical advisors do not support creating new MS–DRGs for cases that identify patients diagnosed with cerebral infarction or intracranial hemorrhage who require mechanical ventilation with or without a thrombolytic and in the absence of an O.R. procedure.

For the first subset of patients (in MS–DRGs 061, 062 and 063), our data findings for MS–DRG 061 demonstrate the 166 cases that reported mechanical ventilation >96 hours had a longer average length of stay (12.8 days versus 6.4 days) and higher average costs ($41,691 versus $20,097) compared to all the cases in MS–DRG 061. However, there were no cases that reported mechanical ventilation >96 hours for MS–DRG 062 or MS–DRG 063. For the 594 cases that reported mechanical ventilation <=96 hours in MS-DRG 061, the data show that the average length of stay was consistent with the average length of stay of all of the cases in MS–DRG 061 (6.5 days versus 6.4 days) and the average costs were also consistent with the average costs of all of the cases in MS-DRG 061 ($23,780 versus $20,097). For the 34 cases that reported mechanical ventilation <=96 hours in MS–DRG 062, the data show that the average length of stay was consistent with the average length of stay of all of the cases in MS–DRG 062 (4.2 days versus 3.9 days) and the average costs were also consistent with the average costs of all of the cases in MS DRG 062 ($15,558 versus $13,865). Lastly, for the 8 cases that reported mechanical ventilation <=96 hours in MS–DRG 063, the data show that the average length of stay was consistent with the average length of stay of all of the cases in MS–DRG 063 (2.3 days versus 2.7 days) and the average costs were also consistent with the average costs of all of the cases in MS DRG 063 ($12,467 versus $11,771).

For the second subset of patients (in MS–DRGs 064, 065 and 066), the data findings for the 2,153 cases that reported mechanical ventilation >96 hours in MS–DRG 064 showed a longer average length of stay (13.4 days versus 6.0 days) and higher average costs ($38,262 versus $12,574) compared to all of the cases in MS–DRG 064. However, the 2,153 cases represent only 2.8 percent of all the cases in MS–DRG

064. For the 22 cases that reported mechanical ventilation >96 hours in MS–DRG 065, the data showed a longer average length of stay (10.2 days versus 3.7 days) and higher average costs ($20,759 versus $7,236) compared to all of the cases in MS–DRG 065. However, the 22 cases represent only 0.02 percent of all the cases in MS–DRG 065. For the one case that reported mechanical ventilation >96 hours in MS–DRG 066, the data showed a longer average length of stay (4.0 days versus 2.5 days) and lower average costs ($3,426 versus $5,321) compared to all of the cases in MS–DRG 066. For the 8,794 cases that reported mechanical ventilation <=96 hours in MS–DRG 064, the data showed that the average length of stay was shorter than the average length of stay for all of the cases in MS–DRG 064 (4.9 days versus 6.0 days) and the average costs were consistent with the average costs of all of the cases in MS–DRG 064 ($13,704 versus $12,574). For the 428 cases that reported mechanical ventilation <=96 hours in MS–DRG 065, the data showed that the average length of stay was shorter than the average length of stay for all of the cases in MS–DRG 065 (2.7 days versus 3.7 days) and the average costs were consistent with the average costs of all the cases in MS–DRG 065 ($8,086 versus $7,236). For the 194 cases that reported mechanical ventilation <=96 hours in MS–DRG 066, the data showed that the average length of stay was shorter than the average length of stay for all of the cases in MS–DRG 066 (1.8 days versus 2.5 days) and the average costs were less than the average costs of all of the cases in MS–DRG 066 ($5,141 versus $5,321).

Based on the analysis described above, the current MS–DRG assignment for the cases in MS–DRGs 061, 062, 063, 064, 065 and 066 that identify patients diagnosed with cerebral infarction or intracranial hemorrhage who require mechanical ventilation with or without a thrombolytic and in the absence of an O.R. procedure appears appropriate.

Our clinical advisors also noted that patients requiring mechanical ventilation (in the absence of an O.R. procedure) are known to be more resource intensive and it would not be practical to create new MS–DRGs specifically for this subset of patients diagnosed with an acute neurologic event, given the various indications for which mechanical ventilation may be utilized. If we were to create new MS–DRGs for patients diagnosed with an intracranial hemorrhage or cerebral infarction who require mechanical ventilation, it would not address all of the other patients who also utilize mechanical ventilation resources. It would also necessitate further extensive analysis and evaluation for several other conditions that require mechanical ventilation across each of the 25 MDCs under the ICD–10 MS–DRGs.

To evaluate the frequency in which the use of mechanical ventilation is reported for different clinical scenarios, we examined claims data across each of the 25 MDCs to determine the number of cases reporting the use of mechanical ventilation >96 hours. Our findings are shown in the table below.

MECHANICAL VENTILATION >96 HOURS ACROSS ALL MDCS

MDC	Number of cases	Average length of stay	Average costs
All cases with mechanical ventilation >96 hours	127,626	18.4	$61,056
MDC 1 (Diseases and Disorders of the Nervous System)—Cases with mechanical ventilation >96 hours	13,668	18.3	61,234
MDC 2 (Disease and Disorders of the Eye)—Cases with mechanical ventilation >96 hours	33	22.7	79,080
MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)—Cases with mechanical ventilation >96 hours	602	20.3	62,625
MDC 4 (Diseases and Disorders of the Respiratory System)—Cases with mechanical ventilation >96 hours	27,793	16.6	48,869
MDC 5 (Diseases and Disorders of the Circulatory System)—Cases with mechanical ventilation >96 hours	16,923	20.7	84,565
MDC 6 (Diseases and Disorders of the Digestive System)—Cases with mechanical ventilation >96 hours	6,401	22.4	73,759
MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas)—Cases with mechanical ventilation >96 hours	1,803	24.5	80,477
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)—Cases with mechanical ventilation >96 hours	2,780	22.3	83,271
MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)—Cases with mechanical ventilation >96 hours	390	22.2	68,288
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)—Cases with mechanical ventilation >96 hours	1,168	20.9	60,682
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)—Cases with mechanical ventilation >96 hours	2,325	19.6	57,893
MDC 12 (Diseases and Disorders of the Male Reproductive System)—Cases with mechanical ventilation >96 hours	54	26.8	95,204
MDC 13 (Diseases and Disorders of the Female Reproductive System)—Cases with mechanical ventilation >96 hours	89	24.6	83,319
MDC 14 (Pregnancy, Childbirth and the Puerperium)—Cases with mechanical ventilation >96 hours	22	17.4	56,981
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)—Cases with mechanical ventilation >96 hours	468	20.1	68,658
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)—Cases with mechanical ventilation >96 hours	538	29.7	99,968
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)—Cases with mechanical ventilation >96 hours	48,176	17.3	55,022
MDC 19 (Mental Diseases and Disorders)—Cases with mechanical ventilation >96 hours	54	29.3	52,749
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)—Cases with mechanical ventilation >96 hours	312	20.5	47,637

MECHANICAL VENTILATION >96 HOURS ACROSS ALL MDCS—Continued

MDC	Number of cases	Average length of stay	Average costs
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)—Cases with mechanical ventilation >96 hours	2,436	18.2	57,712
MDC 22 (Burns)—Cases with mechanical ventilation >96 hours	242	34.8	188,704
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)—Cases with mechanical ventilation >96 hours	64	17.7	50,821
MDC 24 (Multiple Significant Trauma)—Cases with mechanical ventilation >96 hours	922	17.6	72,358
MDC 25 (Human Immunodeficiency Virus Infections)—Cases with mechanical ventilation >96 hours	363	19.1	56,688

As shown in the table, the top 5 MDCs with the largest number of cases reporting mechanical ventilation >96 hours are MDC 18, with 48,176 cases; MDC 4, with 27,793 cases; MDC 5, with 16,923 cases; MDC 1, with 13,668 cases; and MDC 6, with 6,401 cases. We note that the claims data demonstrate that the average length of stay is consistent with what we would expect for cases reporting the use of mechanical ventilation >96 hours across each of the 25 MDCs. The top 5 MDCs with the highest average costs for cases reporting mechanical ventilation >96 hours were MDC 22, with average costs of $188,704; MDC 17, with average costs of $99,968; MDC 12, with average costs of $95,204; MDC 5, with average costs of $84,565; and MDC 13, with average costs of $83,319. We note that the data for MDC 8 demonstrated similar results compared to MDC 13 with average costs of $83,271 for cases reporting mechanical ventilation >96 hours. In summary, the claims data reflect a wide variance with regard to the frequency and average costs for cases reporting the use of mechanical ventilation >96 hours.

We also examined claims data across each of the 25 MDCs for the number of cases reporting the use of mechanical ventilation <=96 hours. Our findings are shown in the table below.

MECHANICAL VENTILATION <=96 HOURS ACROSS ALL MDCS

MDC	Number of cases	Average length of stay	Average costs
All cases with mechanical ventilation <=96 hours	266,583	8.5	$26,668
MDC 1 (Diseases and Disorders of the Nervous System)—Cases with mechanical ventilation <=96 hours	29,896	7.4	22,838
MDC 2 (Disease and Disorders of the Eye)—Cases with mechanical ventilation <=96 hours	60	8.4	29,708
MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)—Cases with mechanical ventilation <=96 hours	1,397	9.8	29,479
MDC 4 (Diseases and Disorders of the Respiratory System)—Cases with mechanical ventilation <=96 hours	64,861	7.8	20,929
MDC 5 (Diseases and Disorders of the Circulatory System)—Cases with mechanical ventilation <=96 hours	45,147	8.8	35,818
MDC 6 (Diseases and Disorders of the Digestive System)—Cases with mechanical ventilation <=96 hours	15,629	11.3	33,660
MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas)—Cases with mechanical ventilation <=96 hours	4,678	10.5	31,565
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)—Cases with mechanical ventilation <=96 hours	7,140	10.4	40,183
MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)—Cases with mechanical ventilation <=96 hours	1,036	10.7	26,809
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)—Cases with mechanical ventilation <=96 hours	3,591	9.0	23,863
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)—Cases with mechanical ventilation <=96 hours	5,506	10.2	27,951
MDC 12 (Diseases and Disorders of the Male Reproductive System)—Cases with mechanical ventilation <=96 hours	168	11.5	35,009
MDC 13 (Diseases and Disorders of the Female Reproductive System)—Cases with mechanical ventilation <=96 hours	310	10.8	32,382
MDC 14 (Pregnancy, Childbirth and the Puerperium)—Cases with mechanical ventilation <=96 hours	55	7.6	21,785
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)—Cases with mechanical ventilation <=96 hours	1,171	8.7	26,138
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)—Cases with mechanical ventilation <=96 hours	1,178	15.3	46,335
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)—Cases with mechanical ventilation <=96 hours	69,826	8.5	25,253
MDC 19 (Mental Diseases and Disorders)—Cases with mechanical ventilation <=96 hours	264	10.4	18,805
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)—Cases with mechanical ventilation <=96 hours	918	8.3	19,376
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)—Cases with mechanical ventilation <=96 hours	10,842	6.5	17,843

MECHANICAL VENTILATION <=96 HOURS ACROSS ALL MDCS—Continued

MDC	Number of cases	Average length of stay	Average costs
MDC 22 (Burns)—Cases with mechanical ventilation <=96 hours	353	9.7	45,557
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)—Cases with mechanical ventilation <=96 hours	307	6.6	16,159
MDC 24 (Multiple Significant Trauma)—Cases with mechanical ventilation <=96 hours	1,709	8.8	36,475
MDC 25 (Human Immunodeficiency Virus Infections)—Cases with mechanical ventilation <=96 hours	541	10.4	29,255

As shown in the table, the top 5 MDCs with the largest number of cases reporting mechanical ventilation <=96 hours are MDC 18, with 69,826 cases; MDC 4, with 64,861 cases; MDC 5, with 45,147 cases; MDC 1, with 29,896 cases; and MDC 6, with 15,629 cases. We note that the claims data demonstrate that the average length of stay is consistent with what we would expect for cases reporting the use of mechanical ventilation <=96 hours across each of the 25 MDCs. The top 5 MDCs with the highest average costs for cases reporting mechanical ventilation <=96 hours are MDC 17, with average costs of $46,335; MDC 22, with average costs of $45,557; MDC 8, with average costs of $40,183; MDC 24, with average costs of $36,475; and MDC 5, with average costs of $35,818. Similar to the cases reporting mechanical ventilation >96 hours, the claims data for cases reporting the use of mechanical ventilation <=96 hours also reflect a wide variance with regard to the frequency and average costs. Depending on the number of cases in each MS–DRG, it may be difficult to detect patterns of complexity and resource intensity.

With respect to the requestor's statement that reporting for other purposes, such as quality measures, clinical trials, and Joint Commission and State certification or survey cases, is based on the principal diagnosis, and their belief that patients who present with cerebral infarction or cerebral hemorrhage and acute respiratory failure are currently in conflict for principal diagnosis sequencing because the cerebral infarction or cerebral hemorrhage code is needed as the principal diagnosis for quality reporting and other purposes (however, acute respiratory failure is needed as the principal diagnosis for purposes of appropriate payment under the MS–DRGs), we note that providers are required to assign the principal diagnosis according to the ICD–10–CM Official Guidelines for Coding and Reporting and these assignments are not based on factors such as quality measures or clinical trials indications. Furthermore, we do not base MS–DRG reclassification decisions on those factors. If the cerebral hemorrhage or ischemic cerebral infarction is the reason for admission to the hospital, the cerebral hemorrhage or ischemic cerebral infarction diagnosis code should be assigned as the principal diagnosis.

We acknowledge that new MS–DRGs were created for cases of patients with sepsis requiring mechanical ventilation greater than and less than 96 hours. However, those MS–DRGs (MS–DRG 575 (Septicemia with Mechanical Ventilation 96+ Hours Age >17) and MS–DRG 576 (Septicemia without Mechanical Ventilation 96+ Hours Age >17)) were created several years ago, in FY 2007 (71 FR 47938 through 47939) in response to public comments suggesting alternatives for the need to recognize the treatment for that subset of patients with severe sepsis who exhibit a greater degree of severity and resource consumption as septicemia is a systemic condition, and also as a preliminary step in the transition from the CMS DRGs to MS–DRGs.

We believe that additional analysis and efforts toward a broader approach to refining the MS–DRGs for cases of patients requiring mechanical ventilation across the MDCs involves carefully examining the potential for instability in the relative weights and disrupting the integrity of the MS–DRG system based on the creation of separate MS-DRGs involving small numbers of cases for various indications in which mechanical ventilation may be required.

The second request focused on patients diagnosed with *any* neurological condition classified under MDC 1 requiring mechanical ventilation in the absence of an O.R. procedure and without having received a thrombolytic agent. Because the first request specifically involved analysis for the acute neurological conditions of cerebral infarction and intracranial hemorrhage under MDC 1 and our findings do not support creating new MS–DRGs for those specific conditions, we did not perform separate claims analysis for other conditions classified under MDC 1.

Therefore, we are not proposing to create new MS–DRGs for cases that identify patients diagnosed with neurological conditions classified under MDC 1 who require mechanical ventilation with or without a thrombolytic and in the absence of an O.R. procedure. We are inviting public comments on our proposal.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Pacemaker Insertions

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56804 through 56809), we discussed a request to examine the ICD–10–PCS procedure code combinations that describe procedures involving pacemaker insertions to determine if some procedure code combinations were excluded from the Version 33 ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively) under MDC 5. We finalized our proposal to modify the Version 34 ICD–10 MS–DRG GROUPER logic so the specified procedure code combinations were no longer required for assignment into those MS–DRGs. As a result, the logic for pacemaker insertion procedures was simplified by separating the procedure codes describing cardiac pacemaker device insertions into one list and separating the procedure codes describing cardiac pacemaker lead insertions into another list. Therefore, when any ICD–10–PCS procedure code describing the insertion of a pacemaker device is reported from that specific logic list with any ICD–10–PCS procedure code describing the insertion of a pacemaker lead from that specific logic list (81 FR 56804 through 56806), the case is assigned to MS–DRGs 242, 243, and 244 under MDC 5.

We then discussed our examination of the Version 33 GROUPER logic for MS-DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively) because assignment of cases to these MS–DRGs

also included qualifying ICD–10–PCS procedure code combinations involving pacemaker insertions (81 FR 56806 through 56808). Specifically, the logic for Version 33 ICD–10 MS–DRGs 258 and 259 included ICD–10–PCS procedure code combinations describing the removal of pacemaker devices and the insertion of new pacemaker devices. We finalized our proposal to modify the Version 34 ICD–10 MS–DRG GROUPER logic for MS–DRGs 258 and 259 to establish that a case reporting any procedure code from the list of ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported would be assigned to MS–DRGs 258 and 259 (81 FR 56806 through 56807) under MDC 5. In addition, we pointed out that a limited number of ICD–10–PCS procedure codes describing pacemaker insertion are classified as non-operating room (non-O.R.) codes within the MS–DRGs and that the Version 34 ICD–10 MS–DRG GROUPER logic would continue to classify these procedure codes as non-O.R. codes. We noted that a case reporting any one of these non-O.R. procedure codes describing a pacemaker device insertion without any other procedure code involving a pacemaker lead would be assigned to MS–DRGs 258 and 259. Therefore, the listed procedure codes describing a pacemaker device insertion under MS–DRGs 258 and 259 are designated as non-O.R. affecting the MS–DRG.

Lastly, we discussed our examination of the Version 33 GROUPER logic for MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively), and noted that cases assigned to these MS–DRGs also included lists of procedure code combinations describing procedures involving the removal of pacemaker leads and the insertion of new leads, in addition to lists of single procedure codes describing procedures involving the insertion of pacemaker leads, removal of cardiac devices, and revision of cardiac devices (81 FR 56808). We finalized our proposal to modify the ICD–10 MS–DRG GROUPER logic for MS–DRGs 260, 261, and 262 so that cases reporting any one of the listed ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices are assigned to MS DRGs 260, 261, and 262 under MDC 5. Therefore, the GROUPER logic that required a combination of procedure codes be reported for assignment into MS–DRGs 260, 261 and 262 under Version 33 was no longer required effective with discharges occurring on or after October 1, 2016 (FY 2017) under Version 34 of the ICD–10 MS–DRGs.

We note that while the discussion in the FY 2017 IPPS/LTCH PPS final rule focused on the MS–DRGs involving pacemaker procedures under MDC 5, similar GROUPER logic exists in Version 33 of the ICD–10 MS–DRGs under MDC 1 (Diseases and Disorders of the Nervous System) in MS–DRGs 040, 041 and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator and without CC/MCC, respectively) and MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) in MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without MCC, respectively) where procedure code combinations involving cardiac pacemaker device insertions or removals and cardiac pacemaker lead insertions or removals are required to be reported together for assignment into those MS–DRGs. We also note that, with the exception of when a principal diagnosis is reported from MDC 1, MDC 5, or MDC 21, the procedure codes describing the insertion, removal, replacement, or revision of pacemaker devices are assigned to a medical MS–DRG in the absence of another O.R. procedure according to the GROUPER logic. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 33, which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for complete documentation of the GROUPER logic that was in effect at that time for the Version 33 ICD–10 MS–DRGs discussed earlier.

For FY 2019, we received a request to assign all procedures involving the insertion of pacemaker devices to surgical MS–DRGs, regardless of the principal diagnosis. The requestor recommended that procedures involving pacemaker insertion be grouped to surgical MS–DRGs within the MDC to which the principal diagnosis is assigned, or that they 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). Currently, in Version 35 of the ICD–10 MS–DRGs, procedures involving pacemakers are assigned to MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or Peripheral Neurostimulator and without CC/MCC, respectively) under MDC 1 (Diseases and Disorders of the Nervous System), to MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with MCC and without MCC, respectively), and MS–DRGs 260, 261 and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) under MDC 5 (Diseases and Disorders of the Circulatory System), and to MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively), under MDC 21 (Injuries, Poisoning and Toxic Effects of Drugs), with all other unrelated principal diagnoses resulting in a medical MS–DRG assignment. According to the requestor, the medical MS–DRGs do not provide adequate payment for the pacemaker device, specialized operating suites, time, skills, and other resources involved for pacemaker insertion procedures. Therefore, the requestor recommended that procedures involving pacemaker insertions be grouped to surgical MS–DRGs. We refer readers to the ICD–10 MS–DRG Definitions Manual Version 35, which is available via the Internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending* for complete documentation of the GROUPER logic for the MS–DRGs discussed earlier.

The following procedure codes describe procedures involving the insertion of a cardiac rhythm related device which are classified as a type of pacemaker insertion under the ICD–10 MS–DRGs. These four codes are assigned to MS–DRGs 040, 041, and 042, as well as MS–DRGs 907, 908, and 909, and are designated as O.R. procedures.

ICD–10–PCS code	Code description
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

We examined cases from the September update of the FY 2017 MedPAR claims data for cases involving pacemaker insertion procedures reporting the above ICD–10–PCS codes in MS–DRGs 040, 041 and 042 under MDC 1. Our findings are shown in the following table.

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 1

MS–DRG in MDC 1	Number of cases	Average length of stay	Average costs
MS–DRG 040—All cases	4,462	10.4	$26,877
MS–DRG 040—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	13	14.2	55,624
MS–DRG 040—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	2	3.5	15,826
MS–DRG 040—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	0	0	0
MS–DRG 040—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0
MS–DRG 041—All cases	5,648	5.2	16,927
MS–DRG 041—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	12	6.4	22,498
MS–DRG 041—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	4	5	17,238
MS–DRG 041—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	0	0	0
MS–DRG 041—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0
MS–DRG 042—All cases	2,154	3.1	13,730
MS–DRG 042—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	5	8	18,183
MS–DRG 042—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0
MS–DRG 042—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	0	0	0
MS–DRG 042—Cases with procedure code 0JH83PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach)	0	0	0

The following table is a summary of the findings shown above from our review of MS–DRGs 040, 041 and 042 and the total number of cases reporting a pacemaker insertion procedure.

MS–DRGS FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 1

MS–DRG in MDC 1	Number of cases	Average length of stay	Average costs
MS–DRGs 040, 041, and 042—All cases	12,264	6.7	$19,986
MS–DRGs 040, 041, and 042—Cases with a pacemaker insertion procedure	36	9.1	32,906

We found a total of 12,264 cases in MS–DRGs 040, 041, and 042 with an average length of stay of 6.7 days and average costs of $19,986. We found a total of 36 cases in MS–DRGs 040, 041, and 042 reporting procedure codes describing the insertion of a pacemaker device with an average length of stay of 9.1 days and average costs of $32,906.

We then examined cases involving pacemaker insertion procedures reporting those same four ICD–10–PCS procedure codes 0JH60PZ, 0JH63PZ, 0JH80PZ and 0JH83PZ in MS–DRGs 907, 908, and 909 under MDC 21. Our findings are shown in the following table.

MS–DRGs FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 21

MS–DRG in MDC 21	Number of cases	Average length of stay	Average costs
MS–DRG 907—All cases	7,405	10.1	$28,997
MS–DRG 907—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	7	11.1	60,141
MS–DRG 908—All cases	8,519	5.2	14,282
MS–DRG 908—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	4	3.8	35,678
MS–DRG 909—All cases	3,224	3.1	9,688
MS–DRG 909—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	2	2	42,688

We note that there were no cases found where procedure codes 0JH63PZ, 0JH80PZ or 0JH83PZ were reported in MS–DRGs 907, 908 and 909 under MDC 21 and, therefore, they are not displayed in the table.

The following table is a summary of the findings shown above from our review of MS–DRGs 907, 908, and 909 and the total number of cases reporting a pacemaker insertion procedure.

MS–DRGs FOR CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 21

MS–DRG in MDC 21	Number of cases	Average length of stay	Average costs
MS–DRGs 907, 908 and 909—All cases	19,148	6.7	$19,199
MS–DRGs 907, 908 and 909—Cases with a pacemaker insertion procedure	13	7.5	49,929

We found a total of 19,148 cases in MS–DRGs 907, 908, and 909 with an average length of stay of 6.7 days and average costs of $19,199. We found a total of 13 cases in MS–DRGs 907, 908, and 909 reporting pacemaker insertion procedures with an average length of stay of 7.5 days and average costs of $49,929.

We also examined cases involving pacemaker insertion procedures reporting the following procedure codes that are assigned to MS–DRGs 242, 243, and 244 under MDC 5.

ICD–10–PCS code	Code description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.
0JH607Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH807Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH837Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

Our data findings are shown in the following table. We note that procedure codes displayed with an asterisk (*) in the table are designated as non-O.R. procedures affecting the MS–DRG.

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRG 242—All cases	18,205	6.9	$26,414
MS–DRG 242—Cases with procedure code 0JH604Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach)	2,518	7.7	25,004
MS–DRG 242—Cases with procedure code 0JH605Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach)	306	7.7	24,454
MS–DRG 242—Cases with procedure code 0JH606Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach)	13,323	6.7	25,497
MS–DRG 242—Cases with procedure code 0JH607Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach)	1,528	8.1	37,060
MS–DRG 242—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	5	16.6	59,334
MS–DRG 242—Cases with procedure code 0JH634Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach)	65	8.5	26,789
MS–DRG 242—Cases with procedure code 0JH635Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach)	10	7	35,104
MS–DRG 242—Cases with procedure code 0JH636Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach)	313	6.4	23,699
MS–DRG 242—Cases with procedure code 0JH637Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest Subcutaneous tissue and fascia, percutaneous approach)	82	7.1	35,382
MS–DRG 242—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	2	12.5	32,405
MS–DRG 242—Cases with procedure code 0JH804Z* (Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach)	25	14.4	43,080
MS–DRG 242—Cases with procedure code 0JH805Z* (Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach)	2	4	26,949
MS–DRG 242—Cases with procedure code 0JH806Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach)	50	6.8	25,306
MS–DRG 242—Cases with procedure code 0JH807Z (Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach)	5	21.2	67,908
MS–DRG 242—Cases with procedure code 0JH836Z (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach)	1	5	36,111
MS–DRG 243—All cases	24,586	4	18,669
MS–DRG 243—Cases with procedure code 0JH604Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach)	2,537	4.7	17,118
MS–DRG 243—Cases with procedure code 0JH605Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach)	271	4.4	17,268
MS–DRG 243—Cases with procedure code 0JH606Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach)	19,921	3.9	18,306
MS–DRG 243—Cases with procedure code 0JH607Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach)	1,236	4.4	28,658
MS–DRG 243—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	6	4.2	20,994
MS–DRG 243—Cases with procedure code 0JH634Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach)	55	5.2	16,784
MS–DRG 243—Cases with procedure code 0JH635Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach)	15	4.1	17,938
MS–DRG 243—Cases with procedure code 0JH636Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach)	431	3.7	16,164
MS–DRG 243—Cases with procedure code 0JH637Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach)	58	5	28,926
MS–DRG 243—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	3	8.3	23,717
MS–DRG 243—Cases with procedure code 0JH804Z* (Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach)	10	8.2	20,871
MS–DRG 243—Cases with procedure code 0JH805Z* (Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach)	1	4	15,739
MS–DRG 243—Cases with procedure code 0JH806Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach)	57	4.4	18,787
MS–DRG 243—Cases with procedure code 0JH807Z (Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach)	3	4	19,653
MS–DRG 243—Cases with procedure code 0JH80PZ (Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach)	1	7	16,224
MS–DRG 243—Cases with procedure code 0JH836Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach)	1	2	14,005
MS–DRG 244—All cases	15,974	2.7	15,670
MS–DRG 244—Cases with procedure code 0JH604Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach)	1,045	3.2	14,541

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5—Continued

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRG 244—Cases with procedure code 0JH605Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach)	127	3	13,208
MS–DRG 244—Cases with procedure code 0JH606Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach)	14,092	2.7	15,596
MS–DRG 244—Cases with procedure code 0JH607Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach)	303	2.8	26,221
MS–DRG 244—Cases with procedure code 0JH60PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach)	2	4.5	9,248
MS–DRG 244—Cases with procedure code 0JH634Z* (Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach)	32	2.8	11,525
MS–DRG 244—Cases with procedure code 0JH635Z* (Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach)	1	2	30,100
MS–DRG 244—Cases with procedure code 0JH636Z* (Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach)	320	2.6	13,670
MS–DRG 244—Cases with procedure code 0JH637Z (Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach)	20	2.7	19,218
MS–DRG 244—Cases with procedure code 0JH63PZ (Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach)	1	3	12,120
MS–DRG 244—Cases with procedure code 0JH805Z* (Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach)	1	1	21,604
MS–DRG 244—Cases with procedure code 0JH806Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach)	36	3.2	16,492
MS–DRG 244—Cases with procedure code 0JH836Z* (Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach)	1	3	12,160

The following table is a summary of the findings shown above from our review of MS–DRGs 242, 243, and 244 and the total number of cases reporting a pacemaker insertion procedure.

CASES INVOLVING PACEMAKER INSERTION PROCEDURES IN MDC 5

MS–DRG in MDC 5	Number of cases	Average length of stay	Average costs
MS–DRGs 242, 243 and 244—All cases	58,765	4.6	$20,253
MS–DRGs 242, 243, and 244—Cases with a pacemaker insertion procedure	*58,822	4.6	20,270

*The figure is not adjusted for cases reporting more than one pacemaker insertion procedure code. The figure represents the frequency in which the number of pacemaker insertion procedures was reported.

We found a total of 58,765 cases in MS–DRGs 242, 243, and 244 with an average length of stay of 4.6 days and average costs of $20,253. We found a total of 58,822 cases reporting pacemaker insertion procedures in MS–DRGs 242, 243, and 244 with an average length of stay of 4.6 days and average costs of $20,270. We note that the analysis performed is by procedure code, and because multiple pacemaker insertion procedures may be reported on a single claim, the total number of these pacemaker insertion procedure cases exceeds the total number of all cases found across MS–DRGs 242, 243, and 244 (58,822 procedures versus 58,765 cases).

We then analyzed claims for cases reporting a procedure code describing (1) the insertion of a pacemaker device only, (2) the insertion of a pacemaker lead only, and (3) both the insertion of a pacemaker device and a pacemaker lead across all the MDCs except MDC 5 to determine the number of cases currently grouping to medical MS–DRGs and the potential impact of these cases moving into the surgical unrelated MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively). Our findings are shown in the following table.

PACEMAKER INSERTION PROCEDURES IN MEDICAL MS–DRGS

All MDCs except MDC 5	Number of cases	Average length of stay	Average costs
Procedures for insertion of pacemaker device	2,747	9.5	$29,389
Procedures for insertion of pacemaker lead	2,831	9.4	29,240
Procedures for insertion of pacemaker device with insertion of pacemaker lead	2,709	9.4	29,297

We found a total of 2,747 cases reporting the insertion of a pacemaker device in 177 medical MS–DRGs with an average length of stay of 9.5 days and average costs of $29,389 across all the MDCs except MDC 5. We found a total of 2,831 cases reporting the insertion of a pacemaker lead in 175 medical MS–DRGs with an average length of stay of 9.4 days and average costs of $29,240 across all the MDCs except MDC 5. We found a total of 2,709 cases reporting both the insertion of a pacemaker device and the insertion of a pacemaker lead in 170 medical MS–DRGs with an average length of stay of 9.4 days and average costs of $29,297 across all the MDCs except MDC 5.

We also analyzed claims for cases reporting a procedure code describing the insertion of a pacemaker device with a procedure code describing the insertion of a pacemaker lead in all the surgical MS–DRGs across all the MDCs except MDC 5. Our findings are shown in the following table.

PACEMAKER INSERTION PROCEDURES IN MEDICAL MS–DRGS

All MDCs except MDC 5	Number of cases	Average length of stay	Average costs
Procedures for insertion of pacemaker device with insertion of pacemaker lead	3,667	12.8	$48,856

We found a total of 3,667 cases reporting the insertion of a pacemaker device and the insertion of a pacemaker lead in 194 surgical MS–DRGs with an average length of stay of 12.8 days and average costs of $48,856 across all the MDCs except MDC 5.

For cases where the insertion of a pacemaker device, the insertion of a pacemaker lead or the insertion of both a pacemaker device and lead were reported on a claim grouping to a medical MS–DRG, the average length of stay and average costs were generally higher for these cases when compared to the average length of stay and average costs for all the cases in their assigned MS–DRGs. For example, we found 113 cases reporting both the insertion of a pacemaker device and lead in MS–DRG 378 (G.I. Hemorrhage with CC), with an average length of stay of 7.1 days and average costs of $23,711. The average length of stay for all cases in MS–DRG 378 was 3.6 days and the average cost for all cases in MS–DRG 378 was $7,190. The average length of stay for cases reporting both the insertion of a pacemaker device and lead were twice as long as the average length of stay for all the cases in MS–DRG 378 (7.1 days versus 3.6 days). In addition, the average costs for the cases reporting both the insertion of a pacemaker device and lead were approximately $16,500 higher than the average costs of all the cases in MS–DRG 378 ($23,711 versus $7,190). We refer readers to Table 6P.1c associated with this proposed rule (which is available via the internet on the CMS website) for the detailed report of our findings across the other medical MS–DRGs. We note that the average costs and average length of stay for cases reporting the insertion of a pacemaker device, the insertion of a pacemaker lead or the insertion of both a pacemaker device and lead are reflected in Columns D and E, while the average costs and average length of stay for all cases in the respective MS–DRG are reflected in Columns I and J.

The claims data results from our analysis of this request showed that if we were to support restructuring the GROUPER logic so that pacemaker insertion procedures that include a combination of the insertion of the pacemaker device with the insertion of the pacemaker lead are designated as an O.R. procedure across all the MDCs, we would expect approximately 2,709 cases to move or ''shift'' from the medical MS–DRGs where they are currently grouping into the surgical unrelated MS–DRGs 981, 982, and 983.

Our clinical advisors reviewed the data results and recommended that pacemaker insertion procedures involving a complete pacemaker system (insertion of pacemaker device combined with insertion of pacemaker lead) warrant classification into surgical MS–DRGs because the patients receiving these devices demonstrate greater treatment difficulty and utilization of resources when compared to procedures that involve the insertion of only the pacemaker device or the insertion of only the pacemaker lead. We note that the request we addressed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 24981 through 24984) was to determine if some procedure code combinations were excluded from the ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244. We proposed and, upon considering public comments received, finalized an alternate approach that we believed to be less complicated. We also stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56806) that we would continue to monitor the MS–DRGs for pacemaker insertion procedures as we receive ICD–10 claims data. Upon further review, we believe that recreating the procedure code combinations for pacemaker insertion procedures would allow for the grouping of these procedures to the surgical MS–DRGs, which we believe is warranted to better recognize the resources and complexity of performing these procedures. Therefore, we are proposing to recreate pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion of a pacemaker lead to act as procedure code combination pairs or ''clusters'' in the GROUPER logic that are designated as O.R. procedures outside of MDC 5 when reported together. We are inviting public comments on our proposal.

We also are proposing to designate all the procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code based on the recommendation of our clinical advisors as noted earlier in this section and consistent with how these procedures were classified under the Version 33 ICD–10 MS–DRG GROUPER logic. We are inviting public comments on our proposal.

We refer readers to Table 6P.1d, Table 6P.1e, and Table 6P.1f associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for (1) a complete list of the proposed procedure code combinations or ''pairs''; (2) a complete list of the procedure codes describing the insertion of a pacemaker device; and (3) a complete list of the procedure codes describing the insertion of a pacemaker lead. We are inviting public comments on our lists of procedure codes that we are proposing to include for restructuring the ICD–10 MS–DRG GROUPER logic for pacemaker insertion procedures.

In addition, we are proposing to maintain the current GROUPER logic for MS–DRGs 258 and 259 (Cardiac

Pacemaker Device Replacement with MCC and without MCC, respectively) where the listed procedure codes as shown in the ICD–10 MS–DRG Definitions Manual Version 35, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending,* describing a pacemaker device insertion, continue to be designated as ''non-O.R. affecting the MS–DRG'' because they are reported when a pacemaker device requires replacement and have a corresponding diagnosis from MDC 5. Also, we are proposing to maintain the current GROUPER logic for MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively) so that cases reporting any one of the listed ICD–10–PCS procedure codes as shown in the ICD–10 MS–DRG Definitions Manual Version 35 describing procedures involving pacemakers and related procedures and associated devices will continue to be assigned to those MS–DRGs under MDC 5 because they are reported when a pacemaker device requires revision and they have a corresponding circulatory system diagnosis. We are inviting public comments on our proposal.

We note that, while the requestor did not include the following procedure codes in its request, these codes are also currently designated as O.R. procedure codes and are assigned to MS–DRGs 260, 261, and 262 under MDC 5.

ICD–10–PCS code	Code description
02PA0MZ	Removal of cardiac lead from heart, open approach.
02PA3MZ	Removal of cardiac lead from heart, percutaneous approach.
02PA4MZ	Removal of cardiac lead from heart, percutaneous endoscopic approach.
02WA0MZ	Revision of cardiac lead in heart, open approach.
02WA3MZ	Revision of cardiac lead in heart, percutaneous approach.
02WA4MZ	Revision of cardiac lead in heart, percutaneous endoscopic approach.
0JPT0PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach.
0JPT3PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, percutaneous approach.
0JWT0PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach.
0JWT3PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach.

We are soliciting public comments on whether these procedure codes describing the removal or revision of a cardiac lead and removal or revision of a cardiac rhythm related (pacemaker) device should also be designated as non-O.R. procedure codes for FY 2019 when reported as a single, individual stand-alone code with a principal diagnosis outside of MDC 5 for consistency in the classification among these devices.

We also note that, while the requestor did not include the following procedure codes in its request, the codes in the following table became effective October 1, 2016 (FY 2017) and also describe procedures involving the insertion of a pacemaker. Specifically, the following list includes procedure codes that describe an intracardiac or ''leadless'' pacemaker. These procedure codes are designated as O.R. procedure codes and are currently assigned to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively) under MDC 5.

ICD–10–PCS code	Code description
02H40NZ	Insertion of intracardiac pacemaker into coronary vein, open approach.
02H43NZ	Insertion of intracardiac pacemaker into coronary vein, percutaneous approach.
02H44NZ	Insertion of intracardiac pacemaker into coronary vein, percutaneous endoscopic approach.
02H60NZ	Insertion of intracardiac pacemaker into right atrium, open approach.
02H63NZ	Insertion of intracardiac pacemaker into right atrium, percutaneous approach.
02H64NZ	Insertion of intracardiac pacemaker into right atrium, percutaneous endoscopic approach.
02H70NZ	Insertion of intracardiac pacemaker into left atrium, open approach.
02H73NZ	Insertion of intracardiac pacemaker into left atrium, percutaneous approach.
02H74NZ	Insertion of intracardiac pacemaker into left atrium, percutaneous endoscopic approach.
02HK0NZ	Insertion of intracardiac pacemaker into right ventricle, open approach.
02HK3NZ	Insertion of intracardiac pacemaker into right ventricle, percutaneous approach.
02HK4NZ	Insertion of intracardiac pacemaker into right ventricle, percutaneous endoscopic approach.
02HL0NZ	Insertion of intracardiac pacemaker into left ventricle, open approach.
02HL3NZ	Insertion of intracardiac pacemaker into left ventricle, percutaneous Approach.
02HL4NZ	Insertion of intracardiac pacemaker into left ventricle, percutaneous endoscopic approach.
02WA0NZ	Revision of intracardiac pacemaker in heart, open approach.
02WA3NZ	Revision of intracardiac pacemaker in heart, percutaneous approach.
02WA4NZ	Revision of intracardiac pacemaker in heart, percutaneous endoscopic approach.
02WAXNZ	Revision of intracardiac pacemaker in heart, external approach.
02H40NZ	Insertion of intracardiac pacemaker into coronary vein, open approach.
02H43NZ	Insertion of intracardiac pacemaker into coronary vein, percutaneous approach.

We examined claims data for procedures involving an intracardiac pacemaker reporting any of the above codes across all MS–DRGs. Our findings are shown in the following table.

INTRACARDIAC PACEMAKER PROCEDURES

Across all MS–DRGs	Number of cases	Average length of stay	Average costs
Procedures for intracardiac pacemaker	1,190	8.6	$38,576

We found 1,190 cases reporting a procedure involving an intracardiac pacemaker with an average length of stay of 8.6 days and average costs of $38,576. Of these 1,190 cases, we found 1,037 cases in MS–DRGs under MDC 5. We also found that the 153 cases that grouped to MS–DRGs outside of MDC 5 grouped to surgical MS–DRGs; therefore, another O.R. procedure was also reported on the claim. However, we are soliciting public comments on whether these procedure codes describing the insertion and revision of intracardiac pacemakers should also be considered for classification into all surgical unrelated MS–DRGs outside of MDC 5 for FY 2019.

b. Drug-Coated Balloons in Endovascular Procedures

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38111), we discontinued new technology add-on payments for the LUTONIX® and IN.PACT™ Admiral™ drug-coated balloon (DCB) technologies, effective for FY 2018, because the technology no longer met the newness criterion for new technology add-on payments. For FY 2019, we received a request to reassign cases that utilize a drug-coated balloon in the performance of an endovascular procedure involving the treatment of superficial femoral arteries for peripheral arterial disease from the lower severity level MS–DRG 254 (Other Vascular Procedures without CC/MCC) and MS–DRG 253 (Other Vascular Procedures with CC) to the highest severity level MS–DRG 252 (Other Vascular Procedures with MCC). We also received a request to revise the title of MS–DRG 252 to ''Other Vascular Procedures with MCC or Drug-Coated Balloon Implant''.

There are currently 36 ICD–10–PCS procedure codes that describe the performance of endovascular procedures involving treatment of the superficial femoral arteries that utilize a drug-coated balloon, which are listed in the following table.

ICD–10–PCS code	Code description
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

The requestor performed its own analysis of claims data and expressed concern that it found that the average costs of cases using a drug-coated balloon in the performance of percutaneous endovascular procedures involving treatment of patients who have been diagnosed with peripheral arterial disease are significantly higher than the average costs of all of the cases in the MS–DRGs where these procedures are currently assigned. The requestor also expressed concern that payments may no longer be adequate because the new technology add-on payments have been discontinued and may affect patient access to these procedures.

We first examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting any 1 of the 36 ICD–10–PCS procedure codes listed in the immediately preceding table that describe the use of a drug-coated balloon in the performance of endovascular procedures in MS–DRGs 252, 253, and 254. Our findings are shown in the following table.

MS–DRGs FOR OTHER VASCULAR PROCEDURES WITH DRUG-COATED BALLOON

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 252—All cases	33,583	7.6	$23,906
MS–DRG 252—Cases with drug-coated balloon	870	8.8	30,912
MS–DRG 253—All cases	25,714	5.4	18,986
MS–DRG 253—Cases with drug-coated balloon	1,532	5.4	23,051
MS–DRG 254—All cases	12,344	2.8	13,287
MS–DRG 254—Cases with drug-coated balloon	488	2.4	17,445

As shown in this table, there were a total of 33,583 cases in MS–DRG 252, with an average length of stay of 7.6 days and average costs of $23,906. There were 870 cases in MS–DRG 252 reporting the use of a drug-coated balloon in the performance of an endovascular procedure, with an average length of stay of 8.8 days and average costs of $30,912. The total number of cases in MS–DRG 253 was 25,714, with an average length of stay of 5.4 days and average costs of $18,986. There were 1,532 cases in MS–DRG 253 reporting the use of a DCB in the performance of an endovascular procedure, with an average length of stay of 5.4 days and average costs of $23,051. The total number of cases in MS–DRG 254 was 12,344, with an average length of stay of 2.8 days and average costs of $13,287. There were 488 cases in MS–DRG 254 reporting the use of a DCB in the performance of an endovascular procedure, with an average length of stay of 2.4 days and average costs of $17,445.

The results of our data analysis show that there is not a very high volume of cases reporting the use of a drug-coated balloon in the performance of endovascular procedures compared to all of the cases in the assigned MS–DRGs. The data results also show that the average length of stay for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures in MS–DRGs 253 and 254 is lower compared to the average length of stay for all of the cases in the assigned MS–DRGs, while the average length of stay for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures in MS–DRG 252 is slightly higher compared to all of the cases in MS–DRG 252 (8.8 days versus 7.6 days). Lastly, the data results showed that the average costs for cases reporting the use of a drug-coated balloon in the performance of percutaneous endovascular procedures were higher compared to all of the cases in the assigned MS–DRGs. Specifically, for MS–DRG 252, the average costs for cases reporting the use of a DCB in the performance of endovascular procedures were $30,912 versus the average costs of $23,906 for all cases in MS–DRG 252, a difference of $7,006. For MS–DRG 253, the average costs for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures were $23,051 versus the average costs of $18,986 for all cases in MS–DRG 253, a difference of $4,065. For MS–DRG 254, the average costs for cases reporting the use of a drug-coated balloon in the performance of endovascular procedures were $17,445 versus the average costs of $13,287 for all cases in MS–DRG 254, a difference of $4,158.

The following table is a summary of the findings discussed above from our review of MS–DRGs 252, 253 and 254 and the total number of cases that used a drug-coated balloon in the performance of the procedure across MS–DRGs 252, 253, and 254.

MS–DRGs FOR OTHER VASCULAR PROCEDURES AND CASES WITH DRUG-COATED BALLOON

MS–DRG	Number of cases	Average Length of stay	Average costs
MS–DRGs 252, 253, and 254—All cases	71,641	6.0	$20,310
MS–DRGs 252, 253, and 254—Cases with drug-coated balloon	2,890	6.0	24,569

As shown in this table, there were a total of 71,641 cases across MS–DRGs 252, 253, and 254, with an average length of stay of 6.0 days and average costs of $20,310. There were a total of 2,890 cases across MS–DRGs 252, 253, and 254 reporting the use of a drug-coated balloon in the performance of the procedure, with an average length of stay of 6.0 days and average costs of $24,569. The data analysis showed that cases reporting the use of a drug-coated balloon in the performance of the procedure across MS–DRGs 252, 253 and 254 have similar lengths of stay (6.0 days) compared to the average length of stay for all of the cases in MS–DRGs 252, 253, and 254. The data results also showed that the cases reporting the use of a drug-coated balloon in the performance of the procedure across

these MS–DRGs have higher average costs ($24,569 versus $20,310) compared to the average costs for all of the cases across these MS–DRGs.

The results of our claims data analysis and the advice from our clinical advisors do not support reassigning cases reporting the use of a drug-coated balloon in the performance of these procedures from the lower severity level MS–DRGs 253 and 254 to the highest severity level MS–DRG 252 at this time. If we were to reassign cases that utilize a drug-coated balloon in the performance of these types of procedures from MS–DRG 254 to MS–DRG 252, the cases would result in overpayment and also would have a shorter length of stay compared to all of the cases in MS–DRG 252. While the cases reporting the use of a drug-coated balloon in the performance of these procedures are higher compared to the average costs for all cases in their assigned MS–DRGs, it is not by a significant amount. We believe that as use of a drug-coated balloon becomes more common, the costs will be reflected in the data. Our clinical advisors also agreed that it would not be clinically appropriate to reassign cases for patients from the lowest severity level (without CC/MCC) MS–DRG to the highest severity level (with MCC) MS–DRG in the absence of additional data to better determine the resource utilization for this subset of patients. Therefore, for these reasons, we are proposing to not reassign cases reporting the use of a drug-coated balloon in the performance of endovascular procedures from MS–DRGs 253 and 254 to MS–DRG 252. We are inviting public comments on our proposal.

We note that because 24 of the 36 ICD–10–PCS procedure codes describing the use of a drug-coated balloon in the performance of endovascular procedures also include the use of an intraluminal device, we conducted further analysis to determine the number of cases reporting an intraluminal device with the use of a drug-coated balloon in the performance of the procedure versus the number of cases reporting the use of a drug-coated balloon alone. We analyzed the number of cases across MS–DRGs 252, 253, and 254 reporting: (1) The use of an intraluminal device (stent) with use of a drug-coated balloon in the performance of the procedure; (2) the use of a drug-eluting intraluminal device (stent) with the use of a drug-coated balloon in the performance of the procedure; and (3) the use of a drug-coated balloon only in the performance of the procedure. Our findings are shown in the following table.

MS–DRGs FOR OTHER VASCULAR PROCEDURES AND CASES WITH DRUG-COATED BALLOON

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 252, 253 and 254—All cases	71,641	6.0	$20,310
MS–DRGs 252, 253 and 254—Cases with intraluminal device with drug-coated balloon	522	6.0	28,418
MS–DRGs 252, 253 and 254—Cases with drug-eluting intraluminal device with drug-coated balloon	447	6.0	26,098
MS–DRGs 252, 253 and 254—Cases with drug-coated balloon only	2,705	6.1	24,553

As shown in this table, there were a total of 71,641 cases across MS–DRGs 252, 253, and 254, with an average length of stay of 6.0 days and average costs of $20,310. There were 522 cases across MS–DRGs 252, 253, and 254 reporting the use of an intraluminal device with use of a drug-coated balloon in the performance of the procedure, with an average length of stay of 6.0 days and average costs of $28,418. There were 447 cases across MS–DRGs 252, 253, and 254 reporting the use of a drug-eluting intraluminal device with use of a drug-coated balloon in the performance of the procedure, with an average length of stay of 6.0 days and average costs of $26,098. Lastly, there were 2,705 cases across MS–DRGs 252, 253, and 254 reporting the use of a drug-coated balloon alone in the performance of the procedure, with an average length of stay of 6.1 days and average costs of $24,553.

The data showed that the 2,705 cases in MS–DRGs 252, 253, and 254 reporting the use of a drug-coated balloon alone in the performance of the procedure have lower average costs compared to the 969 cases in MS–DRGs 252, 253, and 254 reporting the use of an intraluminal device (522 cases) or a drug-eluting intraluminal device (447 cases) with a drug-coated balloon in the performance of the procedure ($24,553 versus $28,418 and $26,098, respectively). The data also showed that the cases reporting the use of a drug-coated balloon alone in the performance of the procedure have a comparable average length of stay compared to the cases reporting the use of an intraluminal device or a drug-eluting intraluminal device with a drug-coated balloon in the performance of the procedure (6.1 days versus 6.0 days).

In summary, we believe that further analysis of endovascular procedures involving the treatment of superficial femoral arteries for peripheral arterial disease that utilize a drug-coated balloon in the performance of the procedure would be advantageous. As additional claims data become available, we will be able to more fully evaluate the differences in cases where a procedure utilizes a drug-coated balloon alone in the performance of the procedure versus cases where a procedure utilizes an intraluminal device or a drug-eluting intraluminal device in addition to a drug-coated balloon in the performance of the procedure.

5. MDC 6 (Diseases and Disorders of the Digestive System)

a. Benign Lipomatous Neoplasm of Kidney

We received a request to reassign ICD–10–CM diagnosis code D17.71 (Benign lipomatous neoplasm of kidney) from MDC 06 (Diseases and Disorders of the Digestive System) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). The requestor stated that this diagnosis code is used to describe a kidney neoplasm and believed that because the ICD–10–CM code is specific to the kidney, a more appropriate assignment would be under MDC 11. In FY 2015, under the ICD–9–CM classification, there was not a specific diagnosis code for a benign lipomatous neoplasm of the kidney. The only diagnosis code available was ICD–9–CM diagnosis code 214.3 (Lipoma of intra-abdominal organs), which was assigned to MS–DRGs 393, 394, and 395 (Other Digestive System Diagnoses with MCC, with CC, and without CC/MCC, respectively) under MDC 6. Therefore, when we converted from the ICD–9 based MS-DRGs to the ICD-10 MS-DRGs, there was not a specific code available that identified the kidney from which to

replicate. As a result, ICD–10–CM diagnosis code D17.71 was assigned to those same MS–DRGs (MS–DRGs 393, 394, and 395) under MDC 6.

While reviewing the MS–DRG classification of ICD–10–CM diagnosis code D17.71, we also reviewed the MS–DRG classification of another diagnosis code organized in subcategory D17.7, ICD–10–CM diagnosis code D17.72 (Benign lipomatous neoplasm of other genitourinary organ). ICD–10–CM diagnosis code D17.72 is currently assigned under MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) to MS–DRGs 606 and 607 (Minor Skin Disorders with and without MCC, respectively). Similar to the replication issue with ICD–10–CM diagnosis code D17.71, with ICD–10–CM diagnosis code D17.72, under the ICD–9–CM classification, there was not a specific diagnosis code to identify a benign lipomatous neoplasm of genitourinary organ. The only diagnosis code available was ICD–9–CM diagnosis code 214.8 (Lipoma of other specified sites), which was assigned to MS–DRGs 606 and 607 under MDC 09. Therefore, when we converted from the ICD–9 based MS-DRGs to the ICD–10 MS-DRGs, there was not a specific code available that identified another genitourinary organ (other than the kidney) from which to replicate. As a result, ICD–10–CM diagnosis code D17.72 was assigned to those same MS–DRGs (MS–DRGs 606 and 607) under MDC 9.

We are proposing to reassign ICD–10–CM diagnosis code D17.71 from MS–DRGs 393, 394, and 395 (Other Digestive System Diagnoses with MCC, with CC, and without CC/MCC, respectively) under MDC 06 to MS–DRGs 686, 687, and 688 (Kidney and Urinary Tract Neoplasms with MCC, with CC, and without CC/MCC, respectively) under MDC 11 because this diagnosis code is used to describe a kidney neoplasm. We also are proposing to reassign ICD–10–CM diagnosis code D17.72 from MS–DRGs 606 and 607 under MDC 09 to MS–DRGs 686, 687, and 688 under MDC 11 because this diagnosis code is used to describe other types of neoplasms classified to the genitourinary tract that do not have a specific code identifying the site. Our clinical advisors agree that the conditions described by the ICD–10–CM diagnosis codes provide specific anatomic detail involving the kidney and genitourinary tract and, therefore, if reclassified under this proposed MDC and reassigned to these MS–DRGs, would improve the clinical coherence of the patients assigned to these groups.

We are inviting public comments on our proposals.

b. Bowel Procedures

We received a request to reassign the following 8 ICD–10–PCS procedure codes that describe repositioning of the colon and takedown of end colostomy from MS–DRGs 344, 345, and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively):

ICD–10–PCS code	Code description
0DSK0ZZ	Reposition ascending colon, open approach.
0DKL4ZZ	Reposition ascending colon, percutaneous endoscopic approach.
0DSL0ZZ	Reposition transverse colon, open approach.
0DSL4ZZ	Reposition transverse colon, percutaneous endoscopic approach.
0DSM0ZZ	Reposition descending colon, open approach.
0DSM4ZZ	Reposition descending colon, percutaneous endoscopic approach.
0DSN0ZZ	Reposition sigmoid colon, open approach.
0DSN4ZZ	Reposition sigmoid colon, percutaneous endoscopic approach.

The requestor indicated that the resources required for procedures identifying repositioning of specified segments of the large bowel are more closely aligned with other procedures that group to MS–DRGs 329, 330, and 331, such as repositioning of the large intestine (unspecified segment).

We analyzed the claims data from the September 2017 update of the FY 2017 Med PAR file for MS–DRGs 344, 345 and 346 for all cases reporting the 8 ICD-10–PCS procedure codes listed in the table above. Our findings are shown in the following table:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 344—All cases	1,452	9.5	$20,609
MS–DRG 344—All cases with a specific large bowel reposition procedure	52	9.6	23,409
MS–DRG 345—All cases	2,674	5.6	11,552
MS–DRG 345—All cases with a specific large bowel reposition	246	6	14,915
MS–DRG 346—All cases	990	3.8	8,977
MS–DRG 346—All cases with a specific large bowel reposition procedure	223	4.5	12,279

The data showed that the average length of stay and average costs for cases that reported a specific large bowel reposition procedure were generally consistent with the average length of stay and average costs for all of the cases in their assigned MS–DRG.

We then examined the claims data in the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 329, 330 and 331. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 329, 330, and 331—All cases	112,388	8.4	$21,382
MS–DRG 329—All cases	33,640	13.3	34,015
MS–DRG 330—All cases	52,644	7.3	17,896
MS–DRG 331—All cases	26,104	4.1	12,132

As shown in this table, across MS–DRGs 329, 330, and 331, we found a total of 112,388 cases, with an average length of stay of 8.4 days and average costs of $21,382. The results of our analysis indicate that the resources required for cases reporting the specific large bowel repositioning procedures are more aligned with those resources required for all cases assigned to MS–DRGs 344, 345, and 346, with the average costs being lower than the average costs for all cases assigned to MS–DRGs 329, 330, and 331. Our clinical advisors also indicated that the 8 specific bowel repositioning procedures are best aligned with those in MS–DRGs 344, 345, and 346. Therefore, we are proposing to maintain the current assignment of the 8 specific bowel repositioning procedures in MS-DRGs 344, 345, and 346 for FY 2019. We are inviting public comments on this proposal.

In conducting our analysis of MS–DRGs 329, 330, and 331, we also examined the subset of cases reporting one of the bowel procedures listed in the following table as the only O.R. procedure.

ICD–10–PCS code	Code description
0DQK0ZZ	Repair ascending colon, open approach.
0DQK4ZZ	Repair ascending colon, percutaneous endoscopic approach.
0DQL0ZZ	Repair transverse colon, open approach.
0DQL4ZZ	Repair transverse colon, percutaneous endoscopic approach.
0DQM0ZZ	Repair descending colon, open approach.
0DQM4ZZ	Repair descending colon, percutaneous endoscopic approach.
0DQN0ZZ	Repair sigmoid colon, open approach.
0DQN4ZZ	Repair sigmoid colon, percutaneous endoscopic approach.
0DSB0ZZ	Reposition ileum, open approach.
0DSB4ZZ	Reposition ileum, percutaneous endoscopic approach.
0DSE0ZZ	Reposition large intestine, open approach.
0DSE4ZZ	Reposition large intestine, percutaneous endoscopic approach.

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. As shown in the following table, we identified 398 cases reporting a bowel procedure as the only O.R. procedure, with an average length of stay of 6.3 days and average costs of $13,595 across MS–DRGs 329, 330, and 331, compared to the overall average length of stay of 8.4 days and average costs of $21,382 for all cases in MS–DRGs 329, 330, and 331.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 329, 330 and 331—All cases	112,388	8.4	$21,382
MS–DRGs 329, 330 and 331—All cases with a bowel procedure as only O.R. procedure	398	6.3	13,595
MS–DRG 329—All cases	33,640	13.3	34,015
MS–DRG 329—Cases with a bowel procedure as only O.R. procedure	86	8.3	19,309
MS–DRG 330—All cases	52,644	7.3	17,896
MS–DRG 330—Cases with a bowel procedure as only O.R. procedure	183	6.9	13,617
MS–DRG 331—All cases	26,104	4.1	12,132
MS–DRG 331—Cases with a bowel procedure as only O.R. procedure	129	4.3	9,754

The resources required for these cases are more aligned with the resources required for cases assigned to MS–DRGs 344, 345, and 346 than with the resources required for cases assigned to MS–DRGs 329, 330, and 331. Our clinical advisors also agreed that these cases are more clinically aligned with cases in MS–DRGs 344, 345, and 346, as they are minor procedures relative to the major bowel procedures assigned to MS–DRGs 329, 330, and 331. Therefore, we are proposing to reassign the 12 ICD–10–PCS procedure codes listed above from MS–DRGs 329, 330, and 331 to MS–DRGs 344, 345, and 346. We are inviting public comments on this proposal.

6. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Spinal Fusion

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38036), we announced our plans to review the ICD–10 logic for the MS–DRGs where procedures involving spinal fusion are currently assigned for FY 2019. After publication of the FY 2018 IPPS/LTCH PPS final rule, we

received a comment suggesting that CMS publish findings from this review and discuss possible future actions. The commenter agreed that it is important to be able to fully evaluate the MS–DRGs to which all spinal fusion procedures are currently assigned with additional claims data, particularly considering the 33 clinically invalid codes that were identified through the rulemaking process (82 FR 38034 through 38035) and the 87 codes identified from the upper and lower joint fusion tables in the ICD–10–PCS classification and discussed at the September 12, 2017 ICD–10 Coordination and Maintenance Committee that were proposed to be deleted effective October 1, 2018 (FY 2019). The agenda and handouts from that meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.*

According to the commenter, deleting the 33 procedure codes describing clinically invalid spinal fusion procedures for FY 2018 partially resolves the issue for data used in setting the FY 2020 payment rates. However, the commenter also noted that the problem will not be fully resolved until the FY 2019 claims are available for FY 2021 ratesetting (due to the 87 codes identified at the ICD–10 Coordination and Maintenance Committee meeting for deletion effective October 1, 2018 (FY 2019)).

The commenter noted that it analyzed claims data from the FY 2016 MedPAR data set and was surprised to discover a significant number of discharges reporting 1 of the 87 clinically invalid codes that were identified and discussed by the ICD–10 Coordination and Maintenance Committee among the following spinal fusion MS–DRGs.

MS–DRG	Description
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.

In addition, the commenter noted that it also identified a number of discharges for the 33 clinically invalid codes we identified in the FY 2018 IPPS/LTCH PPS final rule in the same MS–DRGs listed above. According to the commenter, its findings of these invalid spinal fusion procedure codes in the FY 2016 claims data comprise approximately 30 percent of all discharges for spinal fusion procedures.

The commenter expressed its appreciation that CMS is making efforts to address coding inaccuracies within the classification and suggested that CMS publish findings from its own review of spinal fusion coding issues in those MS–DRGs where cases reporting spinal fusion procedures are currently assigned and include a discussion of possible future actions in the FY 2019 IPPS/LTCH PPS proposed rule. The commenter believed that such an approach would allow time for stakeholder input on any possible proposals along with time for the invalid codes to be worked out of the datasets. The commenter also noted that publishing CMS' findings will put the agency, as well as the public, in a better position to address any potential payment issues for these services beginning in FY 2021.

We thank the commenter for acknowledging the steps we have taken in our efforts to address coding inaccuracies within the classification as we continue to refine the ICD–10 MS–DRGs. We are not proposing any changes to the MS–DRGs involving spinal fusion procedures for FY 2019. However, in response to the commenter's suggestion and findings, we are providing the results from our analysis of the September 2017 update of the FY 2017 MedPAR claims data for the MS–DRGs involving spinal fusion procedures.

We note that while the commenter stated that 87 codes were identified from the upper and lower joint fusion tables in the ICD–10–PCS classification and discussed at the September 12, 2017 ICD–10 Coordination and Maintenance Committee meeting to be deleted effective October 1, 2018 (FY 2019), there were 99 spinal fusion codes identified in the meeting materials, as shown in Table 6P.1g associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

As shown in Table 6P.1g associated with this proposed rule, the 99 procedure codes describe spinal fusion procedures that have device value ''Z'' representing No Device for the 6th character in the code. Because a spinal fusion procedure always requires some type of device (for example, instrumentation with bone graft or bone graft alone) to facilitate the fusion of vertebral bones, these codes are considered clinically invalid and were proposed for deletion at the September 12, 2017 ICD–10 Coordination and Maintenance Committee meeting. We received public comments in support of the proposal to delete the 99 codes describing a spinal fusion without a device, in addition to receiving support for the deletion of other procedure codes describing fusion of body sites other than the spine. A total of 213 procedure codes describing fusion of a specific body part with device value ''Z'' No Device are being deleted effective October 1, 2018 (FY 2019) as shown in Table 6D.—Invalid Procedure Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html).*

We examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting any of the clinically invalid spinal fusion procedures with device value ''Z'' No Device in MS–DRGs 028 (Spinal Procedures with MCC), 029 (Spinal Procedures with CC or Spinal Neurostimulators), and 030 (Spinal Procedures without CC/MCC) under

MDC 1 and MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473 under MDC 8 (that are listed and shown earlier in this section). Our findings are shown in the following tables.

SPINAL FUSION PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 028—All cases	1,927	11.7	$37,524
MS–DRG 028—Cases with invalid spinal fusion procedures	132	13	52,034
MS–DRG 029—All cases	3,426	5.7	22,525
MS–DRG 029—Cases with invalid spinal fusion procedures	171	7.4	33,668
MS–DRG 030—All cases	1,578	3	15,984
MS–DRG 030—Cases with invalid spinal fusion procedures	52	2.6	22,471
MS–DRG 453—All cases	2,891	9.5	70,005
MS–DRG 453—Cases with invalid spinal fusion procedures	823	10.1	84,829
MS–DRG 454—All cases	12,288	4.7	47,334
MS–DRG 454—Cases with invalid spinal fusion procedures	2,473	5.4	59,814
MS–DRG 455—All cases	12,751	3	37,440
MS–DRG 455—Cases with invalid spinal fusion procedures	2,332	3.2	45,888
MS–DRG 456—All cases	1,439	11.5	66,447
MS–DRG 456—Cases with invalid spinal fusion procedures	404	12.5	71,385
MS–DRG 457—All cases	3,644	6	48,595
MS–DRG 457—Cases with invalid spinal fusion procedures	960	6.7	53,298
MS–DRG 458—All cases	1,368	3.6	37,804
MS–DRG 458—Cases with invalid spinal fusion procedures	244	4.1	43,182
MS–DRG 459—All cases	4,904	7.8	43,862
MS–DRG 459—Cases with invalid spinal fusion procedures	726	9	49,387
MS–DRG 460—All cases	59,459	3.4	29,870
MS–DRG 460—Cases with invalid spinal fusion procedures	5,311	3.9	31,936
MS–DRG 471—All cases	3,568	8.4	36,272
MS–DRG 471—Cases with invalid spinal fusion procedures	389	9.9	43,014
MS–DRG 472—All cases	15,414	3.2	21,836
MS–DRG 472—Cases with invalid spinal fusion procedures	1,270	4	25,780
MS–DRG 473—All cases	18,095	1.8	17,694
MS–DRG 473—Cases with invalid spinal fusion procedures	1,185	2.3	19,503

SUMMARY TABLE FOR SPINAL FUSION PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 028, 029, 030, 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473—All cases	142,752	3.9	$31,788
MS–DRGs 028, 029, 030, 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473—Cases with invalid spinal fusion procedures	16,472	5.1	42,929

As shown in this summary table, we found a total of 142,752 cases in MS–DRGs 028, 029, 030, 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473 with an average length of stay of 3.9 days and average costs of $31,788. We found a total of 16,472 cases reporting a procedure code for an invalid spinal fusion procedure with device value ''Z'' No Device across MS–DRGs 028, 029, and 030 under MDC 1 and MS–DRGs 453, 454, 455, 456, 457, 458, 459, 460, 471, 472, and 473 under MDC 8, with an average length of stay of 5.1 days and average costs of $42,929. The results of the data analysis demonstrate that these invalid spinal fusion procedures represent approximately 12 percent of all discharges across the spinal fusion MS–DRGs. Because these procedure codes describe clinically invalid procedures, we would not expect these codes to be reported on any claims data. It is unclear why providers assigned procedure codes for spinal fusion procedures with the device value ''Z'' No Device. Our analysis did not examine whether these claims were isolated to a specific provider or whether this inaccurate reporting was widespread among a number of providers.

With regard to possible future action, we will continue to monitor the claims data for resolution of the coding issues previously identified. Because the procedure codes that we analyzed and presented findings for in this FY 2019 IPPS/LTCH PPS proposed rule are no longer in the classification effective October 1, 2018 (FY 2019), the claims data that we examine for FY 2020 may still contain claims with the invalid codes. As such, we will continue to collaborate with the AHA as one of the four Cooperating Parties through the AHA's *Coding Clinic for ICD–10–CM/PCS* and provide further education on spinal fusion procedures and the proper reporting of the ICD–10–PCS spinal fusion procedure codes. We agree with the commenter that until these coding inaccuracies are no longer reflected in the claims data, it would be premature to propose any MS–DRG modifications for spinal fusion procedures. Possible MS–DRG modifications may include taking into account the approach that was utilized in performing the spinal fusion procedure (for example, open versus percutaneous).

For the reasons described, stated earlier in our discussion, we are proposing to not make any changes to the spinal fusion MS–DRGs for FY 2019.

We are inviting public comments on our proposal.

7. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast): Cellulitis With Methicillin Resistant Staphylococcus Aureus (MSRA) Infection

We received a request to reassign ICD–10–CM diagnosis codes reported with a primary diagnosis of cellulitis and a secondary diagnosis code of B95.62 (Methicillin resistant Staphylococcus aureus infection as the cause of diseases classified elsewhere) or A49.02 (Methicillin resistant Staphylococcus aureus infection, unspecified site). Currently, these cases are assigned to MS–DRG 602 (Cellulitis with MCC) and MS–DRG 603 (Cellulitis without MCC) in MDC 9. The requestor believed that cases of cellulitis with MSRA infection should be reassigned to MS–DRG 867 (Other Infectious and Parasitic Diseases Diagnoses with MCC) because MS–DRGs 602 and 603 include cases that do not accurately reflect the severity of illness or risk of mortality for patients diagnosed with cellulitis and MRSA. The requestor acknowledged that the organism is not to be coded before the localized infection, but stated in its request that patients diagnosed with cellulitis and MRSA are entirely different from patients diagnosed only with cellulitis. The requestor stated that there is a genuine threat to life or limb in these cases. The requestor further stated that, with the opioid crisis and the frequency of MRSA infection among this population, cases of cellulitis with MRSA should be identified with a specific combination code and assigned to MS–DRG 867.

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for all cases assigned to MS–DRGs 602 and 603 and subsets of these cases reporting a primary ICD–10–CM diagnosis of cellulitis and a secondary diagnosis code of B95.62 or A49.02. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 602—All cases	26,244	5.8	$10,034
MS–DRG 603—All cases	104,491	3.9	6,128
MS–DRGs 602 and 603—Cases reported with a primary diagnosis of cellulitis and a secondary diagnosis of B95.62	5,364	5.3	8,245
MS–DRGs 602 and 603—Cases reported with a primary diagnosis of cellulitis and a secondary diagnosis of A49.02	309	5.4	8,832

As shown in this table, we examined the subsets of cases in MS–DRGs 602 and 603 reported with a primary diagnosis of cellulitis and a secondary diagnosis code B95.62 or A49.02. Both of these subsets of cases had an average length of stay that was comparable to the average length of stay for all cases in MS–DRG 602 and greater than the average length of stay for all cases in MS–DRG 603, and average costs that were lower than the average costs of all cases in MS–DRG 602 and higher than the average costs of all cases in MS–DRG 603. As we have discussed in prior rulemaking (77 FR 53309), it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. It is expected that there will be higher cost and lower cost subsets, especially when a subset has low numbers.

To examine the request to reassign ICD–10–CM diagnosis codes reported with a primary diagnosis of cellulitis and a secondary diagnosis code of B95.62 or A49.02 from MS–DRGs 602 and 603 to MS–DRG 867 (which would typically involve also reassigning those cases to the two other severity level MS–DRGs 868 and 869 (Other Infectious and Parasitic Diseases Diagnoses with CC and Other Infectious and Parasitic Diseases Diagnoses without CC/MCC, respectively)), we then analyzed the data for all cases in MS–DRGs 867, 868 and 869. The results of our analysis are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 867–All cases	2,653	7.5	$14,762
MS–DRG 868–All cases	2,096	4.4	7,532
MS–DRG 869–All cases	499	3.3	5,624

We compared the average length of stay and average costs for MS–DRGs 867, 868, and 869 to the average length of stay and average costs for the subsets of cases in MS–DRGs 602 and 603 reported with a primary diagnosis of cellulitis and a secondary diagnosis code of B95.62 or A49.02. We found that the average length of stay for these subsets of cases was shorter and the average costs were lower than those for all cases in MS–DRG 867, but that the average length of stay and average costs were higher than those for all cases in MS–DRG 868 and MS–DRG 869. Our findings from the analysis of claims data do not support reassigning cellulitis cases reported with ICD–10–CM diagnosis code B95.62 or A49.02 from MS–DRGs 602 and 603 to MS–DRGs 867, 868 and 869. Our clinical advisors noted that when a primary diagnosis of cellulitis is accompanied by a secondary diagnosis of B95.62 or A49.02 in MS–DRGs 602 or 603, the combination of these primary and secondary diagnoses is the reason for the hospitalization, and the level of acuity of these subsets of patients is similar to other patients in MS–DRGs 602 and 603. Therefore, these cases are more clinically aligned with all cases in MS–DRGs 602 and 603. For these reasons, we are not proposing to reassign cellulitis cases reported with ICD–10–CM diagnosis code of B95.62 or A49.02 to MS–DRG 867, 868, or 869 for FY 2019. We are inviting public comments on our proposal to maintain the current MS–DRG assignment for ICD–10–CM codes B95.62 and A49.02 when reported as secondary diagnoses with a primary diagnosis of cellulitis.

8. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): Acute Intermittent Porphyria

We received a request to revise the MS–DRG classification for cases of

patients diagnosed with porphyria and reported with ICD–10–CM diagnosis code E80.21 (Acute intermittent (hepatic) porphyria) to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders (''porphyrias'') that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others are acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin. Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection). ICD–10–CM diagnosis code E80.21 is currently assigned to MS–DRG 642 (Inborn and Other Disorders of Metabolism). (We note that this issue has been discussed previously in the FY 2013 IPPS/LTCH PPS proposed and final rules (77 FR 27904 through 27905 and 77 FR 53311 through 53313, respectively) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28016 and 79 FR 49901, respectively).)

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for cases assigned to MS–DRG 642. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 642—All cases	1,801	4.3	$9,157
MS–DRG 642—Cases reporting diagnosis code E80.21 as principal diagnosis	183	5.6	19,244
MS–DRG 642—Cases not reporting diagnosis code E80.21 as principal diagnosis	1,618	4.1	8,016

As shown in this table, cases reporting diagnosis code E80.21 as the principal diagnosis in MS–DRG 642 had higher average costs and longer average lengths of stay compared to the average costs and lengths of stay for all other cases in MS–DRG 642.

To examine the request to reassign cases with ICD–10–CM diagnosis code E80.21 as the principal diagnosis, we analyzed claims data for all cases in MS–DRGs for endocrine disorders, including MS–DRG 643 (Endocrine Disorders with MCC), MS-DRG 644 (Endocrine Disorders with CC), and MS–DRG 645 (Endocrine Disorders without CC/MCC). The results of our analysis are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 643—All cases	9,337	6.3	$11,268
MS–DRG 644—All cases	11,306	4.2	7,154
MS–DRG 645—All cases	4,297	3.2	5,406

The data results showed that the average length of stay for the subset of cases reporting ICD–10–CM diagnosis code E80.21 as the principal diagnosis in MS–DRG 642 is lower than the average length of stay for all cases in MS–DRG 643, but higher than the average length of stay for all cases in MS–DRGs 644 and 645. The average costs for the subset of cases reporting ICD–10–CM diagnosis code E80.21 as the principal diagnosis in MS–DRG 642 are much higher than the average costs for all cases in MS–DRGs 643, 644, and 645. However, after considering these findings in the context of the current MS–DRG structure, we were unable to identify an MS–DRG that would more closely parallel these cases with respect to average costs and length of stay that would also be clinically aligned. Our clinical advisors believe that, in the current MS–DRG structure, the clinical characteristics of patients in these cases are most closely aligned with the clinical characteristics of patients in all cases in MS–DRG 642. Moreover, given the small number of porphyria cases, we do not believe there is justification for creating a new MS–DRG. Basing a new MS–DRG on such a small number of cases could lead to distortions in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. In summary, we are not proposing to revise the MS–DRG classification for porphyria cases. We are inviting public comments on our proposal to maintain porphyria cases in MS–DRG 642.

9. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Admit for Renal Dialysis

We received a request to review the codes assigned to MS–DRG 685 (Admit for Renal Dialysis) to determine if the MS–DRG should be deleted, or if it should remain as a valid MS–DRG. Currently, the ICD–10–CM diagnosis codes shown in the table below are assigned to MS–DRG 685:

ICD–10–CM code	ICD–CM code title
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter.
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter.
Z49.31	Encounter for adequacy testing for hemodialysis.
Z49.32	Encounter for adequacy testing for peritoneal dialysis.

The requestor stated that, under ICD–9–CM, diagnosis code V56.0 (Encounter for extracorporeal dialysis) was reported as the principal diagnosis to identify patients who were admitted for an encounter for dialysis. However, under ICD–10–CM, there is no comparable code in which to replicate such a diagnosis. The requestor noted that, while patients continue to be admitted under inpatient status (under certain circumstances) for dialysis services, there is no existing ICD–10–CM diagnosis code within the classification that specifically identifies a patient being admitted for an encounter for dialysis services.

The requestor also noted that three of the four ICD–10–CM diagnosis codes currently assigned to MS–DRG 685 are on the ''Unacceptable Principal Diagnosis'' edit code list in the Medicare Code Editor (MCE). Therefore, these codes are not allowed to be reported as a principal diagnosis for an inpatient admission.

We examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32. Our findings are shown in the following table.

ADMIT FOR RENAL DIALYSIS ENCOUNTER

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 685—All cases	78	4	$8,871
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.01	78	4	8,871
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.02	0	0	0
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.31	0	0	0
MS–DRG 685—Cases reporting ICD–10–CM diagnosis code Z49.32	0	0	0

As shown in the table above, for MS–DRG 685, there were a total of 78 cases reporting ICD–10–CM diagnosis code Z49.01, with an average length of stay of 4 days and average costs of $8,871. There were no cases reporting ICD–10–CM diagnosis code Z49.02, Z49.31, or Z49.32.

Our clinical advisors reviewed the clinical issues, as well as the claims data for MS–DRG 685. Based on their review of the data analysis, our clinical advisors recommended that MS–DRG 685 be deleted and ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32 be reassigned. Historically, patients were admitted as inpatients to receive hemodialysis services. However, over time, that practice has shifted to outpatient and ambulatory settings. Because of this change in medical practice, we do not believe that it is appropriate to maintain a vestigial MS–DRG, particularly due to the fact that the transition to ICD–10 has resulted in three out of four codes that map to the MS–DRG being precluded from being used as principal diagnosis codes on the claim. In addition, our clinical advisors believe that reassigning the ICD–10–CM diagnosis codes from MS–DRG 685 to MS–DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC\MCC, respectively) is clinically appropriate because the reassignment will result in an accurate MS–DRG assignment of a specific case or inpatient service and encounter based on acceptable principal diagnosis codes under these MS–DRGs.

Therefore, for FY 2019, because there is no existing ICD–10–CM diagnosis code within the classification system that specifically identifies a patient being admitted for an encounter for dialysis services and three of the four ICD–10–CM diagnosis codes, Z49.02, Z49.31, and Z49.32, currently assigned to MS–DRG 685 are on the Unacceptable Principal Diagnosis edit code list in the Medicare Code Editor (MCE), we are proposing to delete MS–DRG 685 and reassign ICD–10–CM diagnosis codes Z49.01, Z49.02, Z49.31, and Z49.32 from MS–DRG 685 to MS–DRGs 698, 699, and 700.

We are inviting public comments on our proposals.

10. MDC 14 (Pregnancy, Childbirth and the Puerperium)

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19834) and final rule (82 FR 38036 through 38037), we noted that the MS–DRG logic involving a vaginal delivery under MDC 14 is technically complex as a result of the requirements that must be met to satisfy assignment to the affected MS–DRGs. As a result, we solicited public comments on further refinement to the following four MS–DRGs related to vaginal delivery: MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C); MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C); MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis); and MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis). In addition, we sought public comments on further refinements to the conditions defined as a complicating diagnosis in MS–DRG 774 and MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications). We indicated that we would review public comments received in response to the solicitation as we continued to evaluate these MS–DRGs under MDC 14 and, if warranted, we would propose refinements for FY 2019. Commenters were instructed to direct comments for consideration to the CMS MS–DRG Classification Change Request Mailbox located at *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

In response to our solicitation for public comments on the MS–DRGs related to vaginal delivery, one commenter recommended that CMS convene a workgroup that would include hospital staff and physicians to systematically review the MDC 14 MS–DRGs and to identify which conditions should appropriately be considered complicating diagnoses. As an interim step, this commenter recommended that CMS consider the following suggestions as a result of its own evaluation of MS–DRGs 767, 774 and 775.

For MS–DRG 767, the commenter recommended that the following ICD–10–CM diagnosis codes and ICD–10–PCS procedure code be removed from the GROUPER logic and provided the rationale for why the commenter suggested removing each code.

SUGGESTIONS FOR MS–DRG 767

[Vaginal delivery with sterilization and/or D&C]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 767
O66.41	Failed attempted vaginal birth after previous cesarean delivery.	This code indicates that the attempt at vaginal delivery has failed.
O71.00	Rupture of uterus before onset of labor, unspecified trimester.	This code indicates that the uterus has ruptured before onset of labor and therefore, a vaginal delivery would not be possible.
O82	Encounter for cesarean delivery without indication	This code indicates the encounter is for a cesarean delivery.
O75.82	Onset (spontaneous) of labor after 37 weeks of gestation but before 39 completed weeks, with delivery by (planned) C-section.	This code indicates this is a cesarean delivery.

SUGGESTIONS FOR MS–DRG 767

[Vaginal delivery with sterilization and/or D&C]

ICD–10–PCS code	Code description	Rationale for removing code from MS–DRG 767
10A07Z6	Abortion of products of conception, vacuum, via natural or artificial opening.	This code indicates the procedure to be an abortion rather than a vaginal delivery.

For MS–DRG 774, the commenter recommended that the following ICD–10–CM diagnosis codes be removed from the GROUPER logic and provided the rationale for why the commenter suggested removing each code.

SUGGESTIONS FOR MS–DRG 774

[Vaginal delivery with Complicating Diagnoses]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 774
O66.41	Failed attempted vaginal birth after previous cesarean delivery.	This code indicates that the attempt at vaginal delivery has failed.
O71.00	Rupture of uterus before onset of labor, unspecified trimester.	This code indicates that the uterus has ruptured before onset of labor and therefore, a vaginal delivery would not be possible.
O75.82	Onset (spontaneous) of labor after 37 weeks of gestation but before 39 completed weeks, with delivery by (planned) C-section.	This code indicates this is a planned cesarean delivery.
O82	Encounter for cesarean delivery without indication	This code indicates the encounter is for a cesarean delivery.
O80	Encounter for full-term uncomplicated delivery	According to the Official Guidelines for Coding and Reporting, ''Code O80 should be assigned when a woman is admitted for a full term normal delivery and delivers a single, healthy infant without any complications antepartum, during the delivery, or postpartum during the delivery episode.''

For MS–DRG 775, the commenter recommended that the following ICD–10–CM diagnosis codes and ICD–10–PCS procedure code be removed from the GROUPER logic and provided the rationale for why the commenter suggested removing each code.

SUGGESTIONS FOR MS–DRG 775

[Vaginal delivery without complicating diagnoses]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 775
O66.41	Failed attempted vaginal birth after previous cesarean delivery.	This code indicates that the attempt at vaginal delivery has failed.
O69.4XX0	Labor and delivery complicated by vasa previa, not applicable or unspecified.	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.

SUGGESTIONS FOR MS–DRG 775—Continued

[Vaginal delivery without complicating diagnoses]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 775
O69.4XX2	Labor and delivery complicated by vasa previa, fetus 2	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX3	Labor and delivery complicated by vasa previa, fetus 3	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX4	Labor and delivery complicated by vasa previa, fetus 4	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX5	Labor and delivery complicated by vasa previa, fetus 5	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O69.4XX9	Labor and delivery complicated by vasa previa, other fetus	According to the physicians consulted, vasa previa always results in C-section. Research indicates that when vasa previa is diagnosed, C-section before labor begins can save the baby's life.
O71.00	Rupture of uterus before onset of labor, unspecified trimester.	This code indicates that the uterus has ruptured before onset of labor and therefore, a vaginal delivery would not be possible.
O82	Encounter for cesarean delivery without indication	This code indicates the encounter is for a cesarean delivery.

SUGGESTIONS FOR MS–DRG 775

[Vaginal delivery without Complicating Diagnosis]

ICD–10–CM code	Code description	Rationale for removing code from MS–DRG 775
10A07Z6	Abortion of Products of Conception, Vacuum, Via Natural or Artificial Opening.	This code indicates the procedure to be an abortion rather than a vaginal delivery.

Another commenter agreed that the MS–DRG logic for a vaginal delivery under MDC 14 is technically complex and provided examples to illustrate these facts. For instance, the commenter noted that the GROUPER logic code lists appear redundant with several of the same codes listed for different MS–DRGs and that the GROUPER logic code list for a vaginal delivery in MS–DRG 774 is comprised of diagnosis codes while the GROUPER logic code list for a vaginal delivery in MS–DRG 775 is comprised of procedure codes. The commenter also noted that several of the ICD–10–CM diagnosis codes shown in the table below that became effective with discharges on and after October 1, 2016 (FY 2017) or October 1, 2017 (FY 2018) appear to be missing from the GROUPER logic code lists for MS–DRGs 781 and 774.

ICD–10–CM code	Code description
O11.4	Pre-existing hypertension with pre-eclampsia, complicating childbirth.
O11.5	Pre-existing hypertension with pre-eclampsia, complicating the puerperium.
012.04	Gestational edema, complicating childbirth.
012.05	Gestational edema, complicating the puerperium.
012.14	Gestational proteinuria, complicating childbirth.
012.15	Gestational proteinuria, complicating the puerperium.
012.24	Gestational edema with proteinuria, complicating childbirth.
012.25	Gestational edema with proteinuria, complicating the puerperium.
O13.4	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating childbirth.
O13.5	Gestational [pregnancy-induced] hypertension without significant proteinuria, complicating the puerperium.
O14.04	Mild to moderate pre-eclampsia, complicating childbirth.
O14.05	Mild to moderate pre-eclampsia, complicating the puerperium.
O14.14	Severe pre-eclampsia, complicating childbirth.
O14.15	Severe pre-eclampsia, complicating the puerperium.
O14.24	HELLP syndrome, complicating childbirth.
O14.25	HELLP syndrome, complicating the puerperium.
O14.94	Unspecified pre-eclampsia, complicating childbirth.
O14.95	Unspecified pre-eclampsia, complicating the puerperium.
O15.00	Eclampsia complicating pregnancy, unspecified trimester.

ICD–10–CM code	Code description
O15.02	Eclampsia complicating pregnancy, second trimester.
O15.03	Eclampsia complicating pregnancy, third trimester.
O15.1	Eclampsia complicating labor.
O15.2	Eclampsia complicating puerperium, second trimester.
O16.4	Unspecified maternal hypertension, complicating childbirth.
O16.5	Unspecified maternal hypertension, complicating the puerperium.
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs.
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs.
O24.435	Gestational diabetes mellitus in puerperium, controlled by oral hypoglycemic drugs.
O44.20	Partial placenta previa NOS or without hemorrhage, unspecified trimester.
O44.21	Partial placenta previa NOS or without hemorrhage, first trimester.
O44.22	Partial placenta previa NOS or without hemorrhage, second trimester.
O44.23	Partial placenta previa NOS or without hemorrhage, third trimester.
O44.30	Partial placenta previa with hemorrhage, unspecified trimester.
O44.31	Partial placenta previa with hemorrhage, first trimester.
O44.32	Partial placenta previa with hemorrhage, second trimester.
O44.33	Partial placenta previa with hemorrhage, third trimester.
O44.40	Low lying placenta NOS or without hemorrhage, unspecified trimester.
O44.41	Low lying placenta NOS or without hemorrhage, first trimester.
O44.42	Low lying placenta NOS or without hemorrhage, second trimester.
O44.43	Low lying placenta NOS or without hemorrhage, third trimester.
O44.50	Low lying placenta with hemorrhage, unspecified trimester.
O44.51	Low lying placenta with hemorrhage, first trimester.
O44.52	Low lying placenta with hemorrhage, second trimester.
O44.53	Low lying placenta with hemorrhage, third trimester.
O70.20	Third degree perineal laceration during delivery, unspecified.
O70.21	Third degree perineal laceration during delivery, IIIa.
O70.22	Third degree perineal laceration during delivery, IIIb.
O70.23	Third degree perineal laceration during delivery, IIIc.
O86.11	Cervicitis following delivery.
O86.12	Endometritis following delivery.
O86.13	Vaginitis following delivery.
O86.19	Other infection of genital tract following delivery.
O86.20	Urinary tract infection following delivery, unspecified.
O86.21	Infection of kidney following delivery.
O86.22	Infection of bladder following delivery.
O86.29	Other urinary tract infection following delivery.
O86.81	Puerperal septic thrombophlebitis.
O86.89	Other specified puerperal infections.

Lastly, the commenter stated that the list of ICD–10–PCS procedure codes appears comprehensive, but indicated that inpatient coding is not their expertise. We note that it was not clear which list of procedure codes the commenter was specifically referencing. The commenter did not provide a list of any procedure codes for CMS to review or reference a specific MS–DRG in its comment.

Another commenter expressed concern that ICD–10–PCS procedure codes 10D17Z9 (Manual extraction of products of conception, retained, via natural or artificial opening) and 10D18Z9 (Manual extraction of products of conception, retained, via natural or artificial opening endoscopic) are not assigned to the appropriate MS–DRG. ICD–10–PCS procedure codes 10D17Z9 and 10D18Z9 describe the manual removal of a retained placenta and are currently assigned to MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C). According to the commenter, a patient that has a vaginal delivery with manual removal of a retained placenta is not having a sterilization or D&C procedure. The commenter noted that, under ICD–9–CM, a vaginal delivery with manual removal of retained placenta grouped to MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis) or MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis). The commenter suggested CMS review these procedure codes for appropriate MS–DRG assignment under the ICD–10 MS–DRGs.

We thank the commenters and appreciate the recommendations and suggestions provided in response to our solicitation for comments on the GROUPER logic for the MS–DRGs involving a vaginal delivery or complicating diagnosis under MDC 14. With regard to the commenter who recommended that we convene a workgroup that would include hospital staff and physicians to systematically review the MDC 14 MS–DRGs and to identify which conditions should appropriately be considered complicating diagnoses, we note that we formed an internal workgroup comprised of clinical advisors that included physicians, coding specialists, and other IPPS policy staff that assisted in our review of the GROUPER logic for a vaginal delivery and complicating diagnoses. We also received clinical input from 3M/Health Information Systems (HIS) staff, which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. We note that our analysis involved other MS–DRGs under MDC 14, in addition to those for which we specifically solicited public comments. As one of the other commenters correctly pointed out, there is redundancy, with several of the same codes listed for different MS–DRGs. Below we provide a summary of our internal analysis with responses to the commenters' recommendations and suggestions incorporated into the applicable sections. We refer readers to the ICD–10 MS–DRG Version 35 Definitions Manual located via the Internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending for documentation of the GROUPER logic associated with the MDC 14 MS–DRGs to assist in the review of our discussion that follows.

We started our evaluation of the GROUPER logic for the MS–DRGs under MDC 14 by first reviewing the current concepts that exist. For example, there are ''groups'' for cesarean section procedures, vaginal delivery procedures, and abortions. There also are groups where no delivery occurs, and lastly, there are groups for after the delivery occurs, or the ''postpartum'' period. These groups are then further subdivided based on the presence or absence of complicating conditions or the presence of another procedure. We examined how we could simplify some of the older, complex GROUPER logic and remain consistent with the structure of other ICD–10 MS–DRGs. We identified the following MS–DRGs for closer review, in addition to MS–DRG 767, MS–DRG 768, MS–DRG 774, MS–DRG 775 and MS–DRG 781.

MS–DRG	Description
MS–DRG 765	Cesarean Section with CC/MCC.
MS–DRG 766	Cesarean Section without CC/MCC.
MS–DRG 769	Postpartum and Post Abortion Diagnoses with O.R. Procedure.
MS–DRG 770	Abortion with D&C, Aspiration Curettage or Hysterotomy.
MS–DRG 776	Postpartum and Post Abortion Diagnoses without O.R. Procedure.
MS–DRG 777	Ectopic Pregnancy.
MS–DRG 778	Threatened Abortion.
MS–DRG 779	Abortion without D&C.
MS–DRG 780	False Labor.
MS–DRG 782	Other Antepartum Diagnoses without Medical Complications.

The first issue we reviewed was the GROUPER logic for complicating conditions (MS–DRGs 774 and 781). Because one of the main objectives in our transition to the MS–DRGs was to better recognize the severity of illness of a patient, we believed we could structure the vaginal delivery and other MDC 14 MS–DRGs in a similar way. Therefore, we began working with the concept of vaginal delivery ''with MCC, with CC and without CC/MCC'' to replace the older, ''complicating conditions'' logic.

Next, we compared the additional GROUPER logic that exists between the vaginal delivery and the cesarean section MS–DRGs (MS–DRGs 765, 766, 767, 774, and 775). Currently, the vaginal delivery MS–DRGs take into account a sterilization procedure; however, the cesarean section MS–DRGs do not. Because a patient can have a sterilization procedure performed along with a cesarean section procedure, we adopted a working concept of ''cesarean section with and without sterilization with MCC, with CC and without CC/MCC'', as well as ''vaginal delivery with and without sterilization with MCC, with CC and without CC/MCC''.

We then reviewed the GROUPER logic for the MS–DRGs involving abortion and where no delivery occurs (MS–DRGs 770, 777, 778, 779, 780, and 782). We believed that we could consolidate the groups in which no delivery occurs.

Finally, we considered the GROUPER logic for the MS–DRGs related to the postpartum period (MS–DRGs 769 and 776) and determined that the structure of these MS–DRGs did not appear to require modification.

After we established those initial working concepts for the MS–DRGs discussed above, we examined the list of the ICD–10–PCS procedure codes that comprise the sterilization procedure GROUPER logic for the vaginal delivery MS–DRG 767. We identified the two manual extraction of placenta codes that the commenter had brought to our attention (ICD–10–PCS codes 10D17Z9 and 10D18Z9). We also identified two additional procedure codes, ICD–10–PCS codes 10D17ZZ (Extraction of products of conception, retained, via natural or artificial opening) and 10D18ZZ (Extraction of products of conception, retained, via natural or artificial opening endoscopic) in the list that are not sterilization procedures. Two of the four procedure codes describe manual extraction (removal) of retained placenta and the other two procedure codes describe dilation and curettage procedures. We then identified four more procedure codes in the list that do not describe sterilization procedures. ICD–10–PCS procedure codes 0UDB7ZX (Extraction of endometrium, via natural or artificial opening, diagnostic), 0UDB7ZZ (Extraction of endometrium, via natural or artificial opening), 0UDB8ZX (Extraction of endometrium, via natural or artificial opening endoscopic, diagnostic), and 0UDB8ZZ (Extraction of endometrium, via natural or artificial opening endoscopic) describe dilation and curettage procedures that can be performed for diagnostic or therapeutic purposes. We believe that these ICD–10–PCS procedure codes would be more appropriately assigned to MDC 13 (Diseases and Disorders of the Female Reproductive System) in MS–DRGs 744 and 745 (D&C, Conization, Laparascopy and Tubal Interruption with and without CC/MCC, respectively) and, therefore, removed them from our working list of sterilization and/or D&C procedures. Because the GROUPER logic for MS–DRG 767 includes both sterilization and/or D&C, we agreed that all the other procedure codes currently included under that logic list of sterilization procedures should remain, with the exception of the two identified by the commenter. Therefore, we agree with the commenter that the manual extraction of retained placenta procedure codes should be reassigned to a more clinically appropriate vaginal delivery MS–DRG because they are not describing sterilization procedures.

Our attention then turned to other MDC 14 GROUPER logic code lists starting with the ''CC for C-section'' list under MS–DRGs 765 and 766 (Cesarean Section with and without CC/MCC, respectively). As noted earlier in this section, in conducting our review, we considered how we could utilize the severity level concept (with MCC, with CC, and without CC/MCC) where applicable. Consistent with this approach, we removed the ''CC for C-section'' logic from these MS–DRGs as part of our working concept and efforts to refine MDC 14. We determined it would be less complicated to simply allow the existing ICD–10 MS-DRG CC and MCC code list logic to apply for these MS–DRGs. Next, we reviewed the logic code lists for ''Malpresentation'' and ''Twins'' and concluded that this logic was not necessary for the cesarean section MS–DRGs because these are

describing antepartum conditions and it is the procedure of the cesarean section that determines whether or not a patient would be classified to these MS–DRGs. Therefore, those code lists were also removed for purposes of our working concept. With regard to the ''Operating Room Procedure'' code list, we agreed there should be no changes. However, we note that the title to ICD–10–PCS procedure code 10D00Z0 (Extraction of products of conception, classical, open approach) is being revised effective October 1, 2018, to replace the term ''classical'' with ''high'' and ICD–10–PCS procedure code 10D00Z1 (Extraction of products of conception, low cervical, open approach) is being revised to replace the term ''low cervical'' to ''low''. These revisions are also shown in Table 6F—Revised Procedure Code Titles available via the Internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Next, we reviewed the ''Delivery Procedure'' and ''Delivery Outcome'' GROUPER logic code lists for the vaginal delivery MS–DRGs 767, 768, 774, and 775. We identified ICD–10–PCS procedure code 10A0726 (Abortion of products of conception, vacuum, via natural or artificial opening) and ICD–10–PCS procedure code 10S07ZZ (Reposition products of conception, via natural or artificial opening) under the ''Delivery Procedure'' code list as procedure codes that should not be included because ICD–10–PCS procedure code 10A07Z6 describes an abortion procedure and ICD–10–PCS procedure code 10S07ZZ describes repositioning of the fetus and does not indicate a delivery took place. We also note that, as described earlier in this discussion, a commenter recommended that ICD–10–PCS procedure code 10A07Z6 be removed from the GROUPER logic specifically for MS–DRGs 767 and 775. Therefore, we removed these two procedure codes from the logic code list for ''Delivery Procedure'' in MS–DRGs 767, 768, 774, and 775. We agreed with the commenter that ICD–10–PCS procedure code 10A07Z6 would be more appropriately assigned to one of the Abortion MS–DRGs. For the remaining procedures currently included in the ''Delivery Procedure'' code list we considered which procedures would be expected to be performed during the course of a standard, uncomplicated delivery episode versus those that would reasonably be expected to require additional resources outside of the delivery room. The list of procedure codes we reviewed is shown in the following table.

ICD–10–PCS code	Code description
0DQP7ZZ	Repair rectum, via natural or artificial opening.
0DQQ0ZZ	Repair anus, open approach.
0DQQ3ZZ	Repair anus, percutaneous approach.
0DQQ4ZZ	Repair anus, percutaneous endoscopic approach.
0DQQ7ZZ	Repair anus, via natural or artificial opening.
0DQQ8ZZ	Repair anus, via natural or artificial opening endoscopic.
0DQR0ZZ	Repair anal sphincter, open approach.
0DQR3ZZ	Repair anal sphincter, percutaneous approach.
0DQR4ZZ	Repair anal sphincter, percutaneous endoscopic approach.

While we acknowledge that these procedures may be performed to treat obstetrical lacerations as discussed in prior rulemaking (81 FR 56853), we also believe that these procedures would reasonably be expected to require a separate operative episode and would not be performed immediately at the time of the delivery. Therefore, we removed those procedure codes describing repair of the rectum, anus, and anal sphincter shown in the table above from our working concept list of procedures to consider for a vaginal delivery. Our review of the list of diagnosis codes for the ''Delivery Outcome'' as a secondary diagnosis did not prompt any changes. We agreed that the current list of diagnosis codes continues to appear appropriate for describing the outcome of a delivery.

As the purpose of our analysis and this review was to clarify what constitutes a vaginal delivery to satisfy the ICD–10 MS–DRG logic for the vaginal delivery MS–DRGs, we believed it was appropriate to expect that a procedure code describing the vaginal delivery or extraction of ''products of conception'' procedure and a diagnosis code describing the delivery outcome should be reported on every claim in which a vaginal delivery occurs. This is also consistent with Section I.C.15.b.5 of the ICD–10–CM Official Guidelines for Coding and Reporting, which states ''A code from category Z37, Outcome of delivery, should be included on every maternal record when a delivery has occurred. These codes are not to be used on subsequent records or on the newborn record.'' Therefore, we adopted the working concept that, regardless of the principal diagnosis, if there is a procedure code describing the vaginal delivery or extraction of ''products of conception'' procedure and a diagnosis code describing the delivery outcome, this logic would result in assignment to a vaginal delivery MS–DRG. We note that, as a result of this working concept, there would no longer be a need to maintain the ''third condition'' list under MS–DRG 774. In addition, as noted earlier in this discussion, because we were working with the concept of vaginal delivery ''with MCC, with CC, and without CC/MCC'' to replace the older, ''complicating conditions'' logic, there would no longer be a need to maintain the ''second condition'' list of complicating diagnosis under MS–DRG 774.

We then reviewed the GROUPER logic code list of ''Or Other O.R. procedures'' (MS–DRG 768) to determine if any changes to these lists were warranted. Similar to our analysis of the procedures listed under the ''Delivery Procedure'' logic code list, our examination of the procedures currently described in the ''Or Other O.R. procedures'' procedure code list also considered which procedures would be expected to be performed during the course of a standard, uncomplicated delivery episode versus those that would reasonably be expected to require additional resources outside of the delivery room. Our analysis of all the procedures resulted in the working concept to allow all O.R. procedures to be applicable for assignment to MS–DRG 768, with the exception of the procedure codes for sterilization and/or D&C and ICD–10–PCS procedure codes 0KQM0ZZ (Repair perineum muscle, open approach) and 0UJM0ZZ (Inspection of vulva, open approach),

which we determined would be reasonably expected to be performed during a standard delivery episode and, therefore, assigned to MS–DRG 774 or MS–DRG 775. We also note that, this working concept for MS–DRG 768 would eliminate vaginal delivery cases with an O.R. procedure grouping to the unrelated MS-DRGs because all O.R. procedures would be included in the GROUPER logic procedure code list for ''Or Other O.R. Procedures''.

The next set of MS–DRGs we examined more closely included MS–DRGs 777, 778, 780, 781, and 782. We believed that, because the conditions in these MS–DRGs are all describing antepartum related conditions, we could group the conditions together clinically. Diagnoses described as occurring during pregnancy and diagnoses specifying a trimester or maternal care in the absence of a delivery procedure reported were considered antepartum conditions. We also believed we could better classify these groups of patients based on the presence or absence of a procedure. Therefore, we worked with the concept of ''antepartum diagnoses with and without O.R. procedure''.

As noted earlier in the discussion, we adopted a working concept of ''cesarean section with and without sterilization with MCC, with CC, and without CC/MCC.'' This concept is illustrated in the following table and includes our suggested modifications.

SUGGESTED MODIFICATIONS TO MS–DRGS FOR MDC 14

[Pregnancy, childbirth and the puerperium]

DELETE 2 MS–DRGs:
MS–DRG 765 (Cesarean Section with CC/MCC).
MS–DRG 766 (Cesarean Section without CC/MCC).
CREATE 6 MS–DRGs:
MS–DRG XXX (Cesarean Section with Sterilization with MCC).
MS–DRG XXX (Cesarean Section with Sterilization with CC).
MS–DRG XXX (Cesarean Section with Sterilization without CC/MCC).
MS–DRG XXX (Cesarean Section without Sterilization with MCC).
MS–DRG XXX (Cesarean Section without Sterilization with CC).
MS–DRG XXX (Cesarean Section without Sterilization without CC/MCC).

As shown in the table, we suggest deleting MS–DRGs 765 and 766. We also suggest creating 6 new MS–DRGs that are subdivided by a 3-way severity level split that includes ''with Sterilization'' and ''without Sterilization''.

We also adopted a working concept of ''vaginal delivery with and without sterilization with MCC, with CC, and without CC/MCC''. This concept is illustrated in the following table and includes our suggested modifications.

SUGGESTED MODIFICATIONS TO MS–DRGS FOR MDC 14

[Pregnancy, childbirth and the puerperium]

DELETE 3 MS–DRGs:
MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C).
MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis).
MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis).
CREATE 6 MS–DRGs:
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C with MCC).
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C with CC).
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C without CC/MCC).
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C with MCC).
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C with CC).
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C without CC/MCC).

As shown in the table, we suggest deleting MS–DRGs 767, 774, and 775. We also suggest creating 6 new MS–DRGs that are subdivided by a 3-way severity level split that includes ''with Sterilization/D&C'' and ''without Sterilization/D&C''.

In addition, as indicated above, we believed that we could consolidate the groups in which no delivery occurs. We believe that consolidating MS–DRGs where clinically coherent conditions exist is consistent with our approach to MS–DRG reclassification and our continued refinement efforts. This concept is illustrated in the following table and includes our suggested modifications.

SUGGESTED MODIFICATIONS TO MS–DRGS FOR MDC 14

[Pregnancy, childbirth and the puerperium]

DELETE 5 MS–DRGs:
MS–DRG 777 (Ectopic Pregnancy).
MS–DRG 778 (Threatened Abortion).
MS–DRG 780 (False Labor).
MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications).
MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications).
CREATE 6 MS–DRGs:
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure with MCC).
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure with CC).
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC).
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure with MCC).
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure with CC).
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC).

As shown in the table, we suggest deleting MS–DRGs 777, 778, 780, 781, and 782. We also suggest creating 6 new MS–DRGs that are subdivided by a 3-way severity level split that includes ''with O.R. Procedure'' and ''without O.R. Procedure''.

Once we established each of these fundamental concepts from a clinical perspective, we were able to analyze the data to determine if our initial suggested modifications were supported.

To analyze our suggested modifications for the cesarean section and vaginal delivery MS–DRGs, we examined the claims data from the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 765, 766, 767, 768, 774, and 775.

MS–DRGS FOR MDC 14 PREGNANCY, CHILDBIRTH AND THE PUERPERIUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 765 (Cesarean Section with CC/MCC)—All cases	3,494	4.6	$8,929
MS–DRG 766 (Cesarean Section without CC/MCC)—All cases	1,974	3.1	6,488
MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C)—All cases	351	3.2	7,886
MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C)—All cases	17	6.2	26,164
MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis)—All cases	1,650	3.3	6,046
MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis)—All cases	4,676	2.4	4,769

As shown in the table, there were a total of 3,494 cases in MS–DRG 765, with an average length of stay of 4.6 days and average costs of $8,929. For MS–DRG 766, there were a total of 1,974 cases, with an average length of stay of 3.1 days and average costs of $6,488. For MS–DRG 767, there were a total of 351 cases, with an average length of stay of 3.2 days and average costs of $ 7,886. For MS–DRG 768, there were a total of 17 cases, with an average length of stay of 6.2 days and average costs of $26,164. For MS–DRG 774, there were a total of 1,650 cases, with an average length of stay of 3.3 days and average costs of $6,046. Lastly, for MS–DRG 775, there were a total of 4,676 cases, with an average length of stay of 2.4 days and average costs of $4,769.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the Version 35 ICD–10 MS–DRG GROUPER. The following table reflects our findings for the suggested Cesarean Section MS–DRGs with a 3-way severity level split.

SUGGESTED MS–DRGS FOR CESAREAN SECTION

MS–DRG	Number of cases	Average Length of stay	Average costs
MS–DRG 783 (Cesarean Section with Sterilization with MCC)	178	6.4	$12,977
MS–DRG 784 (Cesarean Section with Sterilization with CC)	511	4.1	8,042
MS–DRG 785 (Cesarean Section with Sterilization without CC/MCC)	475	3.0	6,259
MS–DRG 786 (Cesarean Section without Sterilization with MCC)	707	5.9	11,515
MS–DRG 787 (Cesarean Section without Sterilization with CC)	1,887	4.2	7,990
MS–DRG 788 (Cesarean Section without Sterilization without CC/MCC)	1,710	3.3	6,663

As shown in the table, there were a total of 178 cases for the cesarean section with sterilization with MCC group, with an average length of stay of 6.4 days and average costs of $12,977. There were a total of 511 cases for the cesarean section with sterilization with CC group, with an average length of stay of 4.1 days and average costs of $8,042. There were a total of 475 cases for the cesarean section with sterilization without CC/MCC group, with an average length of stay of 3.0 days and average costs of $6,259. For the cesarean section without sterilization with MCC group there were a total of 707 cases, with an average length of stay of 5.9 days and average costs of $11,515. There were a total of 1,887 cases for the cesarean section without sterilization with CC group, with an average length of stay of 4.2 days and average costs of $7,990. Lastly, there were a total of 1,710 cases for the cesarean section without sterilization without CC/MCC group, with an average length of stay of 3.3 days and average costs of $6,663.

The following table reflects our findings for the suggested Vaginal Delivery MS–DRGs with a 3-way severity level split.

SUGGESTED MS–DRGS FOR VAGINAL DELIVERY

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 796 (Vaginal Delivery with Sterilization/D&C with MCC)	25	6.7	$11,421
MS–DRG 797 (Vaginal Delivery with Sterilization/D&C with CC)	63	2.4	6,065
MS–DRG 798 (Vaginal Delivery with Sterilization/D&C without CC/MCC)	126	2.3	6,697
MS–DRG 805 (Vaginal Delivery without Sterilization/D&C with MCC)	406	5.0	9,605
MS–DRG 806 (Vaginal Delivery without Sterilization/D&C with CC)	1,952	2.9	5,506
MS–DRG 807 (Vaginal Delivery without Sterilization/D&C without CC/MCC)	4,105	2.3	4,601

As shown in the table, there were a total of 25 cases for the vaginal delivery with sterilization/D&C with MCC group, with an average length of stay of 6.7 days and average costs of $11,421. There were a total of 63 cases for the vaginal delivery with sterilization/D&C with CC group, with an average length of stay of 2.4 days and average costs of $6,065. There were a total of 126 cases for vaginal delivery with sterilization/D&C without CC/MCC group, with an average length of stay of 2.3 days and average costs of $6,697. There were a total of 406 cases for the vaginal delivery without sterilization/D&C with MCC group, with an average length of stay of 5.0 days and average costs of $9,605. There were a total of 1,952 cases for the vaginal delivery without sterilization/D&C with CC group, with an average length of stay of 2.9 days and average costs of $5,506. There were a total of 4,105 cases for the vaginal delivery without sterilization/D&C without CC/MCC group, with an average length of stay of 2.3 days and average costs of $4,601.

We then reviewed the claims data from the September 2017 update of the FY 2017 MedPAR file for MS–DRGs 777, 778, 780, 781, and 782. Our findings are shown in the following table.

MS–DRGS FOR MDC 14 PREGNANCY, CHILDBIRTH AND THE PUERPERIUM

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 777 (Ectopic Pregnancy)—All cases	72	1.9	$7,149
MS–DRG 778 (Threatened Abortion)—All cases	205	2.7	4,001

MS–DRGs FOR MDC 14 PREGNANCY, CHILDBIRTH AND THE PUERPERIUM—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 780 (False Labor)—All cases	41	2.1	3,045
MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications)—All cases	2,333	3.7	5,817
MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications)—All cases	70	2.1	3,381

As shown in the table, there were a total of 72 cases in MS–DRG 777, with an average length of stay of 1.9 days and average costs of $7,149. For MS–DRG 778, there were a total of 205 cases, with an average length of stay of 2.7 days and average costs of $4,001. For MS–DRG 780, there were a total of 41 cases, with an average length of stay of 2.1 days and average costs of $3,045. For MS–DRG 781, there were a total of 2,333 cases, with an average length of stay of 3.7 days and average costs of $5,817. Lastly, for MS–DRG 782, there were a total of 70 cases, with an average length of stay of 2.1 days and average costs of $3,381.

To compare and analyze the impact of deleting those 5 MS–DRGs and creating 6 new MS–DRGs, we ran a simulation using the Version 35 ICD–10 MS–DRG GROUPER. Our findings below represent what we found and would expect under the suggested modifications. The following table reflects the MS–DRGs for the suggested Other Antepartum Diagnoses MS–DRGs with a 3-way severity level split.

SUGGESTED MS–DRGs FOR OTHER ANTEPARTUM DIAGNOSES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 817 (Other Antepartum Diagnoses with O.R. Procedure with MCC)	60	5.1	$13,117
MS–DRG 818 (Other Antepartum Diagnoses with O.R. Procedure with CC)	66	4.2	10,483
MS–DRG 819 (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC)	44	1.7	5,904
MS–DRG 831 (Other Antepartum Diagnoses without O.R. Procedure with MCC)	786	4.3	7,248
MS–DRG 832 (Other Antepartum Diagnoses without O.R. Procedure with CC)	910	3.5	4,994
MS–DRG 833 (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC)	855	2.7	3,843

Our analysis of claims data from the September 2017 update of the FY 2017 MedPAR file recognized that when the criteria to create subgroups were applied for the 3-way severity level splits for the suggested MS–DRGs, those criteria were not met in all instances. For example, the criteria that there are at least 500 cases in the MCC or CC group was not met for the suggested Vaginal Delivery with Sterilization/D&C 3-way severity level split or the suggested Other Antepartum Diagnoses with O.R. Procedure 3-way severity level split.

However, as we have noted in prior rulemaking (72 FR 47152), we cannot adopt the same approach to refine the maternity and newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these DRGs. While there is not a high volume of these cases represented in the Medicare data, and while we generally advise that other payers should develop MS–DRGs to address the needs of their patients, we believe that our suggested 3-way severity level splits would address the complexity of the current MDC 14 GROUPER logic for a vaginal delivery and takes into account the new and different clinical concepts that exist under ICD–10 for this subset of patients while also maintaining the existing MS–DRG structure for identifying severity of illness, utilization of resources and complexity of service.

However, as an alternative option, we also performed analysis for a 2-way severity level split for the suggested MS–DRGs. Our findings are shown in the following tables.

SUGGESTED MS–DRGs FOR CESAREAN SECTION

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Cesarean Section with Sterilization with CC/MCC)	689	4.7	$9,317
MS–DRG XXX (Cesarean Section with Sterilization without CC/MCC)	475	3.0	6,259
MS–DRG XXX (Cesarean Section without Sterilization with MCC)	2,594	4.7	8,951
MS–DRG XXX (Cesarean Section without Sterilization without CC/MCC)	1,710	3.3	6,663

SUGGESTED MS–DRGs FOR VAGINAL DELIVERY

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C with CC/MCC)	88	3.6	$7,586
MS–DRG XXX (Vaginal Delivery with Sterilization/D&C without CC/MCC)	126	2.3	6,697
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C with MCC)	2,358	3.2	6,212

SUGGESTED MS–DRGS FOR VAGINAL DELIVERY—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Vaginal Delivery without Sterilization/D&C without CC/MCC)	4,105	2.3	4,601

SUGGESTED MS–DRGS FOR OTHER ANTEPARTUM DIAGNOSES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure with MCC)	126	4.7	$11,737
MS–DRG XXX (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC)	44	1.7	5,904
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure with MCC)	1,696	3.9	6,039
MS–DRG XXX (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC)	855	2.7	3,843

Similar to the analysis performed for the 3-way severity level split, we acknowledge that when the criteria to create subgroups was applied for the alternative 2-way severity level splits for the suggested MS–DRGs, those criteria were not met in all instances. For example, the suggested Vaginal Delivery with Sterilization/D&C and the Other Antepartum Diagnoses with O.R. Procedure alternative option 2-way severity level splits did not meet the criteria for 500 or more cases in the MCC or CC group.

Based on our review, which included support from our clinical advisors, and the analysis of claims data described above, we are proposing the deletion of 10 MS–DRGs and the creation of 18 new MS–DRGs (as shown below). This proposal is based on the approach described above, which involves consolidating specific conditions and concepts into the structure of existing logic and making additional modifications, such as adding severity levels, as part of our refinement efforts for the ICD–10 MS–DRGs. Our proposals are intended to address the vaginal delivery ''complicating diagnosis'' logic and antepartum diagnoses with ''medical complications'' logic with the proposed addition of the existing and familiar severity level concept (with MCC, with CC, and without CC/MCC) to the MDC 14 MS–DRGs to provide the ability to distinguish the varying resource requirements for this subset of patients and allow the opportunity to make more meaningful comparisons with regard to severity across the MS–DRGs. Our proposals, as set forth below, would also simplify the vaginal delivery procedure logic that we identified and commenters acknowledged as technically complex by eliminatng the extensive diagnosis and procedure code lists for several conditions that must be met for assignment to the vaginal delivery MS–DRGs. Our proposals are also intended to respond to issues identified and brought to our attention through public comments for consideration in updating the GROUPER logic code lists in MDC 14.

Specifically, we are proposing to delete the following 10 MS–DRGs under MDC 14:

- MS–DRG 765 (Cesarean Section with CC/MCC);
- MS–DRG 766 (Cesarean Section without CC/MCC);
- MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C);
- MS–DRG 774 (Vaginal Delivery with Complicating Diagnosis);
- MS–DRG 775 (Vaginal Delivery without Complicating Diagnosis);
- MS–DRG 777 (Ectopic Pregnancy);
- MS–DRG 778 (Threatened Abortion);
- MS–DRG 780 (False Labor);
- MS–DRG 781 (Other Antepartum Diagnoses with Medical Complications); and
- MS–DRG 782 (Other Antepartum Diagnoses without Medical Complications).

We are proposing to create the following new 18 MS–DRGs under MDC 14:

- Proposed new MS–DRG 783 (Cesarean Section with Sterilization with MCC);
- Proposed new MS–DRG 784 (Cesarean Section with Sterilization with CC);
- Proposed new MS–DRG 785 (Cesarean Section with Sterilization without CC/MCC);
- Proposed new MS–DRG 786 (Cesarean Section without Sterilization with MCC);
- Proposed new MS–DRG 787 (Cesarean Section without Sterilization with CC);
- Proposed new MS–DRG 788 Cesarean Section without Sterilization without CC/MCC);
- Proposed new MS–DRG 796 (Vaginal Delivery with Sterilization/D&C with MCC);
- Proposed new MS–DRG 797 (Vaginal Delivery with Sterilization/D&C with CC);
- Proposed new MS–DRG 798 (Vaginal Delivery with Sterilization/D&C without CC/MCC);
- Proposed new MS–DRG 805 (Vaginal Delivery without Sterilization/D&C with MCC);
- Proposed new MS–DRG 806 (Vaginal Delivery without Sterilization/D&C with CC);
- Proposed new MS–DRG 807 (Vaginal Delivery without Sterilization/D&C without CC/MCC);
- Proposed new MS–DRG 817 (Other Antepartum Diagnoses with O.R. Procedure with MCC);
- Proposed new MS–DRG 818 (Other Antepartum Diagnoses with O.R. Procedure with CC);
- Proposed new MS–DRG 819 (Other Antepartum Diagnoses with O.R. Procedure without CC/MCC);
- Proposed new MS–DRG 831 (Other Antepartum Diagnoses without O.R. Procedure with MCC);
- Proposed new MS–DRG 832 (Other Antepartum Diagnoses without O.R. Procedure with CC); and
- Proposed new MS–DRG 833 (Other Antepartum Diagnoses without O.R. Procedure without CC/MCC).

The diagrams below illustrate how the proposed MS–DRG logic for MDC 14 would function. The first diagram (Diagram 1.) begins by asking if there is a principal diagnosis from MDC 14. If no, the GROUPER logic directs the case to the appropriate MDC based on the principal diagnosis reported. Next, the logic asks if there is a cesarean section procedure reported on the claim. If yes, the logic asks if there was a sterilization procedure reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 783, 784, or

785. If no, the logic assigns the case to one of the proposed new MS–DRGs 786, 787, or 788. If there was not a cesarean section procedure reported on the claim, the logic asks if there was a vaginal delivery procedure reported on the claim. If yes, the logic asks if there was another O.R. procedure other than sterilization, D&C, delivery procedure or a delivery inclusive O.R. procedure. If yes, the logic assigns the case to existing MS–DRG 768. If no, the logic asks if there was a sterilization and/or D&C reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 796, 797, or 798. If no, the logic assigns the case to one of the proposed new MS–DRGs 805, 806, or 807. If there was not a vaginal delivery procedure reported on the claim, the GROUPER logic directs you to the other non-delivery MS–DRGs as shown in Diagram 2.

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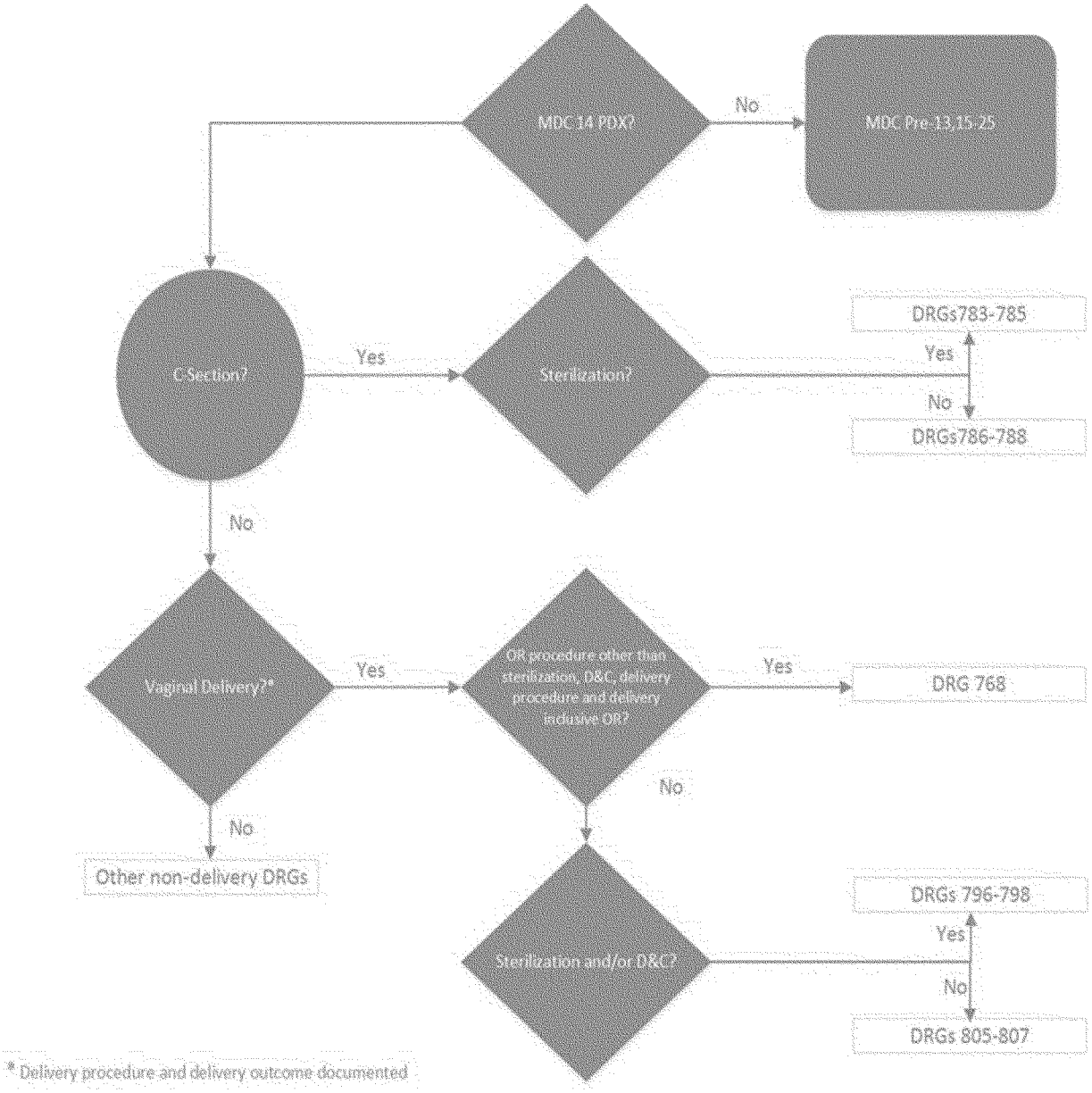
Diagram 1.

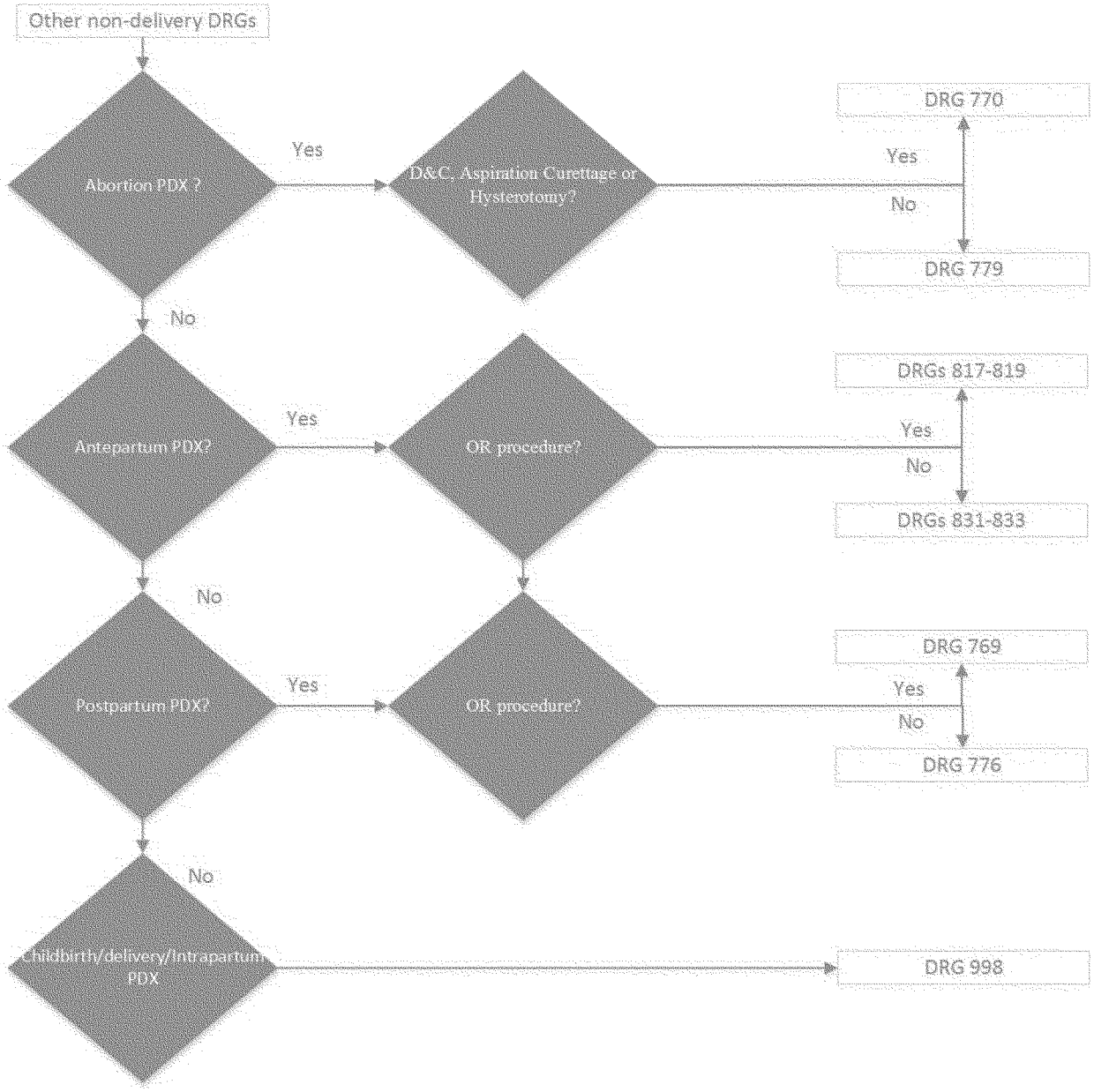


The logic for Diagram 2. begins by asking if there is a principal diagnosis of abortion reported on the claim. If yes, the logic then asks if there was a D&C, aspiration curettage or hysterotomy procedure reported on the claim. If yes, the logic assigns the case to existing MS–DRG 770. If no, the logic assigns the case to existing MS–DRG 779. If there was not a principal diagnosis of abortion reported on the claim, the logic asks if there was a principal diagnosis of an antepartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to one of the proposed new MS–DRGs 817, 818, or 819. If no, the logic assigns the case to one of the proposed new MS–DRGs 831, 832, or 833. If there was not a principal diagnosis of an

antepartum condition reported on the claim, the logic asks if there was a principal diagnosis of a postpartum condition reported on the claim. If yes, the logic then asks if there was an O.R. procedure reported on the claim. If yes, the logic assigns the case to existing MS–DRG 769. If no, the logic assigns the case to existing MS–DRG 776. If there was not a principal diagnosis of a postpartum condition reported on the claim, the logic identifies that there was a principal diagnosis describing childbirth, delivery or an intrapartum condition reported on the claim without any other procedures, and assigns the case to existing MS–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis).

To assist in detecting coding and MS–DRG assignment errors for MS–DRG 998 that could result when a provider does not report the procedure code for either a cesarean section or a vaginal delivery along with an outcome of delivery diagnosis code, as discussed in section II.F.13.d., we are proposing to add a new Questionable Obstetric Admission edit under the MCE. We are inviting public comments on this proposed MCE edit and we also are inviting public comments on the need for any additional MCE considerations with regard to the proposed changes for the MDC 14 MS–DRGs.

Diagram 2



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We refer readers to Tables 6P.1h through 6P.1k for the lists of the diagnosis and procedure codes that we are proposing to assign to the GROUPER logic for the proposed new MS–DRGs and the existing MS–DRGs under MDC

14. We are inviting public comments on our proposed list of diagnosis codes, which also addresses the list of diagnosis codes that a commenter identified as missing from the GROUPER logic. We note that, as a result of our proposed GROUPER logic changes to the vaginal delivery MS–DRGs, which would only take into account the procedure codes for a vaginal delivery and the outcome of delivery secondary diagnosis codes, there is no longer a need to maintain a specific principal diagnosis logic list for those MS–DRGs. Therefore, while we appreciate the detailed suggestions and rationale submitted by the commenter for why specific diagnosis codes should be removed from the vaginal delivery principal diagnosis logic as displayed earlier in this discussion, we are proposing to remove that logic. We are inviting public comments on our proposal.

We also are inviting public comments on our proposal to reassign ICD–10–PCS procedure codes 0UDB7ZX, 0UDB7ZZ, 0UDB8ZX, and 0UDB8ZZ that describe dilation and curettage procedures from MS–DRG 767 under MDC 14 to MS–DRGs 744 and 745 under MDC 13.

In addition, we are inviting public comments on our proposed list of procedure codes for the proposed revised MDC 14 MS–DRG logic, which would require a procedure code for case assignment. Finally, we are inviting public comments on the proposed deletion of the 10 MS–DRGs and the proposed creation of 18 new MS–DRGs with a 3-way severity level split listed above in this section, as well as on the potential alternative new MS–DRGs using a 2-way severity level split as also presented above.

11. MDC 18 (Infectious and Parasitic Diseases (Systematic or Unspecified Sites): Systemic Inflammatory Response Syndrome (SIRS) of Non-Infectious Origin

ICD–10–CM diagnosis codes R65.10 (Systemic Inflammatory Response Syndrome (SIRS) of non-infectious origin without acute organ dysfunction) and R65.11 (Systemic Inflammatory Response Syndrome (SIRS) of non-infectious origin with acute organ dysfunction) are currently assigned to MS–DRGs 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours), 871 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours with MCC), and 872 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours without MCC) under MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites). Our clinical advisors noted that these diagnosis codes are specifically describing conditions of a non-infectious origin, and recommended that they be reassigned to a more clinically appropriate MS–DRG.

We examined claims data from the September 2017 update of the FY 2017 MedPAR file for cases in MS–DRGs 870, 871, and 872. Our findings are shown in the following table.

SEPTICEMIA OR SEVERE SEPSIS WITH AND WITHOUT MECHANICAL VENTILATION >96 HOURS WITH AND WITHOUT MCC

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 870—All cases	31,658	14.3	$42,981
MS–DRG 871—All cases	566,531	6.3	13,002
MS–DRG 872—All cases	150,437	4.3	7,532

As shown in this table, we found a total of 31,658 cases in MS–DRG 870, with an average length of stay of 14.3 days and average costs of $42,981. We found a total of 566,531 cases in MS–DRG 871, with an average length of stay of 6.3 days and average costs of $13,002. Lastly, we found a total of 150,437 cases in MS–DRG 872, with an average length of stay of 4.3 days and average costs of $7,532.

We then examined claims data in MS–DRGs 870, 871, or 872 for cases reporting an ICD–10–CM diagnosis code of R65.10 or R65.11. Our findings are shown in the following table.

SIRS OF NON-INFECTIOUS ORIGIN WITH AND WITHOUT ACUTE ORGAN DYSFUNCTION

MS–DRGs 870, 871 and 872	Number of cases	Average length of stay	Average costs
MS–DRGs 870, 871, and 872—Cases reporting a principal diagnosis code of R65.10	1,254	3.8	$6,615
MS–DRGs 870, 871, and 872—Cases reporting a principal diagnosis code of R65.11	138	4.8	9,655
MS–DRGs 870, 871, and 872—Cases reporting a secondary diagnosis code of R65.10	1,232	5.5	10,670
MS–DRGs 870, 871, and 872—Cases reporting a secondary diagnosis code of R65.11	117	6.2	12,525

As shown in this table, we found a total of 1,254 cases reporting a principal diagnosis code of R65.10 in MS–DRGs 870, 871, and 872, with an average length of stay of 3.8 days and average costs of $6,615. We found a total of 138 cases reporting a principal diagnosis code of R65.11 in MS–DRGs 870, 871, and 872, with an average length of stay of 4.8 days and average costs of $9,655. We found a total of 1,232 cases reporting a secondary diagnosis code of R65.10 in MS–DRGs 870, 871, and 872, with an average length of stay of 5.5 days and average costs of $10,670. Lastly, we found a total of 117 cases reporting a secondary diagnosis code of R65.11 in MS–DRGs 870, 871, and 872, with an average length of stay of 6.2 days and average costs of $12,525.

The claims data included a total of 1,392 cases in MS–DRGs 870, 871, and 872 that reported a principal diagnosis code of R65.10 or R65.11. We note that these 1,392 cases appear to have been coded inaccurately according to the ICD–10–CM Official Guidelines for Coding and Reporting at Section I.C.18.g., which specifically state: ''The systemic inflammatory response syndrome (SIRS) can develop as a result of certain non-infectious disease processes, such as trauma, malignant neoplasm, or pancreatitis. When SIRS is documented with a non-infectious condition, and no subsequent infection

is documented, the code for the underlying condition, such as an injury, should be assigned, followed by code R65.10, Systemic inflammatory response syndrome (SIRS) of non-infectious origin without acute organ dysfunction or code R65.11, Systemic inflammatory response syndrome (SIRS) of non-infectious origin with acute organ dysfunction.'' Therefore, according to the Coding Guidelines, ICD–10–CM diagnosis codes R65.10 and R65.11 should not be reported as the principal diagnosis on an inpatient claim.

We have acknowledged in past rulemaking the challenges with coding for SIRS (and sepsis) (71 FR 24037). In addition, we note that there has been confusion with regard to how these codes are displayed in the ICD–10 MS–DRG Definitions Manual under MS–DRGs 870, 871, and 872, which may also impact the reporting of these conditions. For example, in Version 35 of 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/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending,* the logic for case assignment to MS–DRGs 870, 871, and 872 is comprised of a list of several diagnosis codes, of which ICD–10–CM diagnosis codes R65.10 and R65.11 are included. Because these codes are listed under the heading of ''Principal Diagnosis'', it may appear that these codes are to be reported as a principal diagnosis for assignment to MS–DRGs 870, 871, or 872. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code is for grouping purposes only. The GROUPER (and, therefore, documentation in the MS–DRG Definitions Manual) was not designed to account for coding guidelines or coverage policies. Since the inception of the IPPS, the data editing function has been a separate and independent step in the process of determining a DRG assignment. Except for extreme data integrity issues that prevent a DRG from being assigned, such as an invalid principal diagnosis, the DRG assignment GROUPER does not edit for data integrity. Prior to assigning the MS–DRG to a claim, the MACs apply a series of data integrity edits using programs such as the Medicare Code Editor (MCE). The MCE is designed to identify cases that require further review before classification into an MS–DRG. These data integrity edits address issues such as data validity, coding rules, and coverage policies. The separation of the MS–DRG grouping and data editing functions allows the MS–DRG GROUPER to remain stable during a fiscal year even though coding rules and coverage policies may change during the fiscal year. As such, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38050 through 38051), we finalized our proposal to add ICD–10–CM diagnosis codes R65.10 and R65.11 to the Unacceptable Principal Diagnosis edit in the MCE as a result of the Official Guidelines for Coding and Reporting related to SIRS, in efforts to improve coding accuracy for these types of cases.

To address the issue of determining a more appropriate MS–DRG assignment for ICD–10–CM diagnosis codes R65.10 and R65.11, we reviewed alternative options under MDC 18. Our clinical advisors determined the most appropriate option is MS–DRG 864 (Fever) because the conditions that are assigned here describe conditions of a non-infectious origin.

Therefore, we are proposing to reassign ICD–10–CM diagnosis codes R65.10 and R65.11 to MS–DRG 864 and to revise the title of MS–DRG 864 to ''Fever and Inflammatory Conditions'' to better reflect the diagnoses assigned there.

PROPOSED REVISED MS–DRG 864 (FEVER AND INFLAMMATORY CONDITIONS)

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 864—All cases	12,144	3.4	$6,232

We are inviting public comments on our proposals.

12. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): Corrosive Burns

ICD–10–CM Coding Guidelines include ''Code first'' sequencing instructions for cases reporting a primary diagnosis of toxic effect (ICD–10–CM codes T51 through T65) and a secondary diagnosis of corrosive burn (ICD–10–CM codes T21.40 through T21.79). We received a request to reassign these cases from MS–DRGs 901 (Wound Debridements for Injuries with MCC), 902 (Wound Debridements for Injuries with CC), 903 (Wound Debridements for Injuries without CC/MCC), 904 (Skin Grafts for Injuries with CC/MCC), 905 (Skin Grafts for Injuries without CC/MCC), 917 (Poisoning and Toxic Effects of Drugs with MCC), and 918 (Poisoning and Toxic Effects of Drugs without MCC) to MS–DRGs 927 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation >96 Hours with Skin Graft), 928 (Full Thickness Burn with Skin Graft or Inhalation Injury with CC/MCC), 929 (Full Thickness Burn with Skin Graft or Inhalation Injury without CC/MCC), 933 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation >96 Hours without Skin Graft), 934 (Full Thickness Burn without Skin Graft or Inhalation Injury), and 935 (Nonextensive Burns).

The requestor noted that, for corrosion burns codes T21.40 through T21.79, ICD-10–CM Coding Guidelines instruct to ''Code first (T51 through T65) to identify chemical and intent.'' Because code first notes provide sequencing directive, when patients are admitted with corrosive burns (which can be full thickness and extensive), toxic effect codes T51 through T65 must be sequenced first followed by codes for the corrosive burns. This causes full-thickness and extensive burns to group to MS–DRGs 901 through 905 when excisional debridement and split thickness skin grafts are performed, and to MS–DRGs 917 and 918 when procedures are not performed. This is in contrast to cases reporting a primary diagnosis of corrosive burn, which group to MS-DRGs 927 through 935.

The requestor stated that MS–DRGs 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), and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC) are grouped based on the procedure performed in combination with the principal diagnosis or secondary

diagnosis (secondary scoliosis). The requestor stated that when codes for corrosive burns are reported as secondary diagnoses in conjunction with principal diagnoses codes T5l through T65, particularly when skin grafts are performed, they would be more appropriately assigned to MS–DRGs 927 through 935.

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for all cases assigned to MS–DRGs 901, 902, 903, 904, 905, 917, and 918, and subsets of these cases with primary diagnosis of toxic effect with secondary diagnosis of corrosive burn. We note that we found no cases from this subset in MS-DRGs 903, 907, 908, and 909 and, therefore, did not include the results for these MS-DRGs in the table below. We also analyzed all cases assigned to MS–DRGs 927, 928, 929, 933, 934, and 935 and those cases that reported a primary diagnosis of corrosive burn. Our findings are shown in the following two tables.

MDC 21 Injuries, Poisonings and Toxic Effects of Drugs

MS–DRG	Number of cases	Average length of stay	Average costs
All Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn—Across all MS–DRGs	55	5.5	$18,077
MS–DRG 901—All cases	968	13	31,479
MS–DRG 901—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	1	8	12,388
MS–DRG 902—All cases	1,775	6.6	14,206
MS–DRG 902—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	8	10.3	20,940
MS–DRG 904—All cases	905	9.8	23,565
MS–DRG 904—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	8	6.4	22,624
MS–DRG 905—All cases	263	4.9	13,291
MS–DRG 905—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	2	2.5	7,682
MS–DRG 906—All cases	458	4.8	13,555
MS–DRG 906—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	1	5	7,409
MS–DRG 917—All cases	31,730	4.8	10,280
MS–DRG 917—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	6	4.8	7,336
MS–DRG 918—All cases	19,819	3	5,529
MS–DRG 918—Cases with primary diagnosis of toxic effect and secondary diagnosis of corrosive burn	28	3.5	5,643

As shown in this table, there were a total of 55 cases with a primary diagnosis of toxic effect and a secondary diagnosis of corrosive burn across MS–DRGs 901, 902, 903, 904, 905, 917, and 918. When comparing this subset of codes relative to those of each MS–DRG as a whole, we noted that, in most of these MS–DRGs, the average costs and average length of stay for this subset of cases were roughly equivalent to or lower than the average costs and average length of stay for cases in the MS–DRG as a whole, while in one case, they were higher. As we have noted in prior rulemaking (77 FR 53309) and elsewhere in this rule, it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. It is expected that there will be higher cost and lower cost subsets, especially when a subset has low numbers. The results of this analysis indicate that these cases are appropriately placed within their current MDC.

Our clinical advisors reviewed this request and indicated that patients with a primary diagnosis of toxic effect and a secondary diagnosis of corrosive burn have been exposed to an irritant or corrosive substance and, therefore, are clinically similar to those patients in MDC 21. Furthermore, our clinical advisors do not believe that the size of this subset of cases justifies the significant changes to the GROUPER logic that would be required to address the commenter's request, which would involve rerouting cases when the primary and secondary diagnoses are in different MDCs.

MDC 22 Burns

MS–DRG	Number of cases	Average length of stay	Average costs
All cases with primary diagnosis of corrosive burn—Across all MS–DRGs	60	8.5	$19,456
MS–DRG 927—All cases	159	28.1	128,960
MS–DRG 927—Cases with primary diagnosis of corrosive burn	1	41	75,985
MS–DRG 928—All cases	1,021	15.1	42,868
MS–DRG 928—Cases with primary diagnosis of corrosive burn	13	13.2	31,118
MS–DRG 929—All cases	295	7.9	21,600
MS–DRG 929—Cases with primary diagnosis of corrosive burn	4	12.5	18,527
MS–DRG 933—All cases	121	4.6	21,291
MS–DRG 933—Cases with primary diagnosis of corrosive burn	1	7	91,779
MS–DRG 934—All cases	503	6.1	13,286

MDC 22 BURNS—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 934—Cases with primary diagnosis of corrosive burn	11	5.8	13,280
MS–DRG 935—All cases	1,705	5.2	13,065
MS–DRG 935—Cases with primary diagnosis of corrosive burn	29	5	9,822

To address the request of reassigning cases with a primary diagnosis of toxic effect and secondary diagnosis of corrosive burn, we reviewed the data for all cases in MS–DRGs 927, 928, 929, 933, 934, and 935 and those cases reporting a primary diagnosis of corrosive burn. We found a total of 60 cases reporting a primary diagnosis of corrosive burn, with an average length of stay of 8.5 days and average costs of $19,456. Our clinical advisors believe that these cases reporting a primary diagnosis of corrosive burn are appropriately placed in MDC 22 as they are clinically aligned with other patients in this MDC. In summary, the results of our claims data analysis and the advice from our clinical advisors do not support reassigning cases in MS–DRGs 901, 902, 903, 904, 905, 917, and 918 reporting a primary diagnosis of toxic effect and a secondary diagnosis of corrosive burn to MS–DRGs 927, 928, 929, 933, 934 and 935. Therefore, we are not proposing to reassign these cases. We are inviting public comments on our proposal to maintain the current MS-DRG structure for these cases.

13. 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 2018 IPPS/LTCH PPS final rule (82 FR 38045), we made available the FY 2018 ICD–10 MCE Version 35 manual file. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 35 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* through the FY 2018 IPPS Final Rule Home Page.

For this FY 2019 IPPS/LTCH PPS proposed rule, below we address the MCE requests we received by the November 1, 2017 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 of 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 12–55 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) Perinatal/Newborn Diagnoses Category

Under the ICD–10 MCE, the Perinatal/Newborn Diagnoses category under the Age Conflict edit considers the age of 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 to be inclusive. This includes conditions that have their origin in the fetal or perinatal period (before birth through the first 28 days after birth) even if morbidity occurs later. 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.

In the ICD–10–CM classification, there are 14 diagnosis codes that describe specific suspected conditions that have been evaluated and ruled out during the newborn period and are currently not on the Perinatal/Newborn Diagnoses Category edit code list. We consulted with staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that the following diagnosis codes are appropriate to add to the edit code list for the Perinatal/Newborn Diagnoses Category.

ICD–10–CM code	Code description
Z05.0	Observation and evaluation of newborn for suspected cardiac condition ruled out.
Z05.1	Observation and evaluation of newborn for suspected infectious condition ruled out.
Z05.2	Observation and evaluation of newborn for suspected neurological condition ruled out.
Z05.3	Observation and evaluation of newborn for suspected respiratory condition ruled out.
Z05.41	Observation and evaluation of newborn for suspected genetic condition ruled out.
Z05.42	Observation and evaluation of newborn for suspected metabolic condition ruled out.
Z05.43	Observation and evaluation of newborn for suspected immunologic condition ruled out.
Z05.5	Observation and evaluation of newborn for suspected gastrointestinal condition ruled out.
Z05.6	Observation and evaluation of newborn for suspected genitourinary condition ruled out.
Z05.71	Observation and evaluation of newborn for suspected skin and subcutaneous tissue condition ruled out.

ICD–10–CM code	Code description
Z05.72	Observation and evaluation of newborn for suspected musculoskeletal condition ruled out.
Z05.73	Observation and evaluation of newborn for suspected connective tissue condition ruled out.
Z05.8	Observation and evaluation of newborn for other specified suspected condition ruled out.
Z05.9	Observation and evaluation of newborn for unspecified suspected condition ruled out.

Therefore, we are proposing to add the ICD–10–CM diagnosis codes listed in the table above to the Age Conflict edit under the Perinatal/Newborn Diagnoses Category edit code list. We also are proposing to continue to include the existing diagnosis codes currently listed under the Perinatal/Newborn Diagnoses Category edit code list. We are inviting public comments on our proposals.

(2) Pediatric Diagnoses Category

Under the ICD–10 MCE, the Pediatric Diagnoses Category for the Age Conflict edit considers the age range of 0 to 17 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.F.15. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the diagnoses that are no longer effective as of October 1, 2018. Included in this table is an ICD–10–CM diagnosis code currently listed on the Pediatric Diagnoses Category edit code list, ICD–10–CM diagnosis code Z13.4 (Encounter for screening for certain developmental disorders in childhood). We are proposing to remove this code from the Pediatric Diagnoses Category edit code list. We also are proposing to continue to include the other existing diagnosis codes currently listed under the Pediatric Diagnoses Category edit code list. We are inviting public comments on our proposals.

(3) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity Diagnoses Category for the Age Conflict edit considers the age range of 12 to 55 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.F.15. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the new diagnoses codes that have been approved to date, which will be effective with discharges occurring on and after October 1, 2018. The following table lists the new ICD–10–CM diagnosis codes included in Table 6A associated with pregnancy and maternal care that we believe are appropriate to add to the Maternity Diagnoses Category edit code list under the Age Conflict edit. Therefore, we are proposing to add these codes to the Maternity Diagnoses Category edit code list under the Age Conflict edit.

ICD–10–CM code	Code description
F53.0	Postpartum depression.
F53.1	Puerperal psychosis.
O30.131	Triplet pregnancy, trichorionic/triamniotic, first trimester.
O30.132	Triplet pregnancy, trichorionic/triamniotic, second trimester.
O30.133	Triplet pregnancy, trichorionic/triamniotic, third trimester.
O30.139	Triplet pregnancy, trichorionic/triamniotic, unspecified trimester.
O30.231	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, first trimester.
O30.232	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, second trimester.
O30.233	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, third trimester.
O30.239	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, unspecified trimester.
O30.831	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, first trimester.
O30.832	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, second trimester.
O30.833	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, third trimester.
O30.839	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, unspecified trimester.
O86.00	Infection of obstetric surgical wound, unspecified.
O86.01	Infection of obstetric surgical wound, superficial incisional site.
O86.02	Infection of obstetric surgical wound, deep incisional site.
O86.03	Infection of obstetric surgical wound, organ and space site.
O86.04	Sepsis following an obstetrical procedure.
O86.09	Infection of obstetric surgical wound, other surgical site.

In addition, as discussed in section II.F.15. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the diagnosis codes that are no longer effective as of October 1, 2018. Included in this table are two ICD–10–CM diagnosis codes currently listed on the Maternity Diagnoses Category edit code list: ICD–10–CM diagnosis codes F53 (Puerperal psychosis) and O86.0 (Infection of obstetric surgical wound). We are proposing to remove these codes from the Maternity Diagnoses Category Edit code list. We also are proposing to continue to include the other existing diagnosis codes currently listed under the Maternity Diagnoses Category edit

code list. We are inviting public comments on our proposals.

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

We received a request to consider the addition of the following ICD–10–CM diagnosis codes to the list for the Diagnoses for Females Only edit.

ICD–10–CM code	Code description
Z30.015	Encounter for initial prescription of vaginal ring hormonal contraceptive.
Z31.7	Encounter for procreative management and counseling for gestational carrier.
Z98.891	History of uterine scar from previous surgery.

The requestor noted that, currently, ICD–10–CM diagnosis code Z30.44 (Encounter for surveillance of vaginal ring hormonal contraceptive device) is on the Diagnoses for Females Only edit code list and suggested that ICD–10–CM diagnosis code Z30.015, which also describes an encounter involving a vaginal ring hormonal contraceptive, be added to the Diagnoses for Females Only edit code list as well. In addition, the requestor suggested that ICD–10–CM diagnosis codes Z31.7 and Z98.891 be added to the Diagnoses for Females Only edit code list.

We reviewed ICD–10–CM diagnosis codes Z30.015, Z31.7, and Z98.891, and we agree with the requestor that it is clinically appropriate to add these three ICD–10–CM diagnosis codes to the Diagnoses for Females Only edit code list because the conditions described by these codes are specific to and consistent with the female sex.

In addition, as discussed in section II.F.15. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the new diagnosis codes that have been approved to date, which will be effective with discharges occurring on and after October 1, 2018. The following table lists the new diagnosis codes that are associated with conditions consistent with the female sex. We are proposing to add these ICD–10–CM diagnosis codes to the Diagnoses for Females Only edit code list under the Sex Conflict edit.

ICD–10–CM code	Code description
F53.0	Postpartum depression.
F53.1	Puerperal psychosis.
N35.82	Other urethral stricture, female.
N35.92	Unspecified urethral stricture, female.
O30.131	Triplet pregnancy, trichorionic/triamniotic, first trimester.
O30.132	Triplet pregnancy, trichorionic/triamniotic, second trimester.
O30.133	Triplet pregnancy, trichorionic/triamniotic, third trimester.
O30.139	Triplet pregnancy, trichorionic/triamniotic, unspecified trimester.
O30.231	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, first trimester.
O30.232	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, second trimester.
O30.233	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, third trimester.
O30.239	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, unspecified trimester.
O30.831	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, first trimester.
O30.832	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, second trimester.
O30.833	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, third trimester.
O30.839	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, unspecified trimester.
O86.00	Infection of obstetric surgical wound, unspecified.
O86.01	Infection of obstetric surgical wound, superficial incisional site.
O86.02	Infection of obstetric surgical wound, deep incisional site.
O86.03	Infection of obstetric surgical wound, organ and space site.
O86.04	Sepsis following an obstetrical procedure.
O86.09	Infection of obstetric surgical wound, other surgical site.
Q51.20	Other doubling of uterus, unspecified.
Q51.21	Other complete doubling of uterus.
Q51.22	Other partial doubling of uterus.
Q51.28	Other doubling of uterus, other specified.
Z13.32	Encounter for screening for maternal depression.

We are inviting public comments on our proposals.

In addition, as discussed in section II.F.15. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes associated with this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the diagnosis codes that are no longer effective as of October 1, 2018. Included

in this table are the following three ICD–10–CM diagnosis codes currently listed on the Diagnoses for Females Only edit code list.

ICD–10–CM code	Code description
F53	Puerperal psychosis.
O86.00	Infection of obstetric surgical wound.
Q51.20	Other doubling of uterus, unspecified.

Because these three ICD–10–CM diagnosis codes will no longer be effective as of October 1, 2018, we are proposing to remove them from the Diagnoses for Females Only edit code list under the Sex Conflict edit. We are inviting public comments on our proposal.

(2) Procedures for Females Only Edit

As discussed in section II.F.15. of the preamble of this proposed rule, Table 6B.—New Procedure Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the procedure codes that have been approved to date, which will be effective with discharges occurring on and after October 1, 2018. We are proposing to add the three ICD–10–PCS procedure codes in the following table describing procedures associated with the female sex to the Procedures for Females Only edit code list.

ICD–10–CM code	Code description
0UY90Z0	Transplantation of uterus, allogeneic, open approach.
0UY90Z1	Transplantation of uterus, syngeneic, open approach.
0UY90Z2	Transplantation of uterus, zooplastic, open approach.

We also are proposing to continue to include the existing procedure codes currently listed under the Procedures for Females Only edit code list. We are inviting public comments on our proposals.

(3) Diagnoses for Males Only Edit

As discussed in section II.F.15. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the new diagnosis codes that have been approved to date, which will be effective with discharges occurring on and after October 1, 2018. The following table lists the new diagnosis codes that are associated with conditions consistent with the male sex. We are proposing to add these ICD–10–CM diagnosis codes to the Diagnoses for Males Only edit code list under the Sex Conflict edit.

ICD–10–CM code	Code description
N35.016	Post-traumatic urethral stricture, male, overlapping sites.
N35.116	Postinfective urethral stricture, not elsewhere classified, male, overlapping sites.
N35.811	Other urethral stricture, male, meatal.
N35.812	Other urethral bulbous stricture, male.
N35.813	Other membranous urethral stricture, male.
N35.814	Other anterior urethral stricture, male, anterior.
N35.816	Other urethral stricture, male, overlapping sites.
N35.819	Other urethral stricture, male, unspecified site.
N35.911	Unspecified urethral stricture, male, meatal.
N35.912	Unspecified bulbous urethral stricture, male.
N35.913	Unspecified membranous urethral stricture, male.
N35.914	Unspecified anterior urethral stricture, male.
N35.916	Unspecified urethral stricture, male, overlapping sites.
N35.919	Unspecified urethral stricture, male, unspecified site.
N99.116	Postprocedural urethral stricture, male, overlapping sites.
R93.811	Abnormal radiologic findings on diagnostic imaging of right testicle.
R93.812	Abnormal radiologic findings on diagnostic imaging of left testicle.
R93.813	Abnormal radiologic findings on diagnostic imaging of testicles, bilateral.
R93.819	Abnormal radiologic findings on diagnostic imaging of unspecified testicle.

We also are proposing to continue to include the existing diagnosis codes currently listed under the Diagnoses for Males Only edit code list. We are inviting public comments on our proposals.

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.F.15. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS

website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the new diagnosis codes that have been approved to date which will be effective with discharges occurring on and after October 1, 2018. Included in this table are ICD–10–CM diagnosis codes K82.A1 (Gangrene of gallbladder in cholecystitis) and K82.A2 (Perforation of gallbladder in cholecystitis). We are proposing to add these two ICD–10–CM diagnosis codes to the Manifestation Code as Principal Diagnosis edit code list because the type of cholecystitis would be required to be reported first. We also are proposing to continue to include the existing diagnosis codes currently listed under the Manifestation Code as Principal Diagnosis edit code list. We are inviting public comments on our proposals.

d. Questionable Admission Edit

In the MCE, some diagnoses are not usually sufficient justification for admission to an acute care hospital. For example, if a patient is assigned ICD–10–CM diagnosis code R03.0 (Elevated blood pressure reading, without diagnosis of hypertension), the patient would have a questionable admission because an elevated blood pressure reading is not normally sufficient justification for admission to a hospital.

As discussed in section II.F.10. of the preamble of this proposed rule, we are proposing several modifications to the MS–DRGs under MDC 14 (Pregnancy, Childbirth and the Puerperium). One aspect of these proposed modifications involves the GROUPER logic for the cesarean section and vaginal delivery MS–DRGs. We refer readers to section II.F.10. of the preamble of this proposed rule for a detailed discussion of the proposals regarding these MS–DRG modifications under MDC 14 and the relation to the MCE.

If a patient presents to the hospital and either a cesarean section or a vaginal delivery occurs, it is expected that, in addition to the specific type of delivery code, an outcome of delivery code is also assigned and reported on the claim. The outcome of delivery codes are ICD–10–CM diagnosis codes that are to be reported as secondary diagnoses as instructed in Section I.C.15.b.5 of the ICD–10–CM Official Guidelines for Coding and Reporting which states: ''A code from category Z37, Outcome of delivery, should be included on every maternal record when a delivery has occurred. These codes are not to be used on subsequent records or on the newborn record.'' Therefore, to encourage accurate coding and appropriate MS–DRG assignment in alignment with the proposed modifications to the delivery MS–DRGs, we are proposing to create a new ''Questionable Obstetric Admission Edit'' under the Questionable Admission edit to read as follows:

''b. Questionable obstetric admission

ICD–10–PCS procedure codes describing a cesarean section or vaginal delivery are considered to be a questionable admission *except* when reported with a corresponding secondary diagnosis code describing the outcome of delivery.

Procedure code list for cesarean section

10D00Z0 Extraction of Products of Conception, High, Open Approach
10D00Z1 Extraction of Products of Conception, Low, Open Approach
10D00Z2 Extraction of Products of Conception, Extraperitoneal, Open Approach

Procedure code list for vaginal delivery

10D07Z3 Extraction of Products of Conception, Low Forceps, Via Natural or Artificial Opening
10D07Z4 Extraction of Products of Conception, Mid Forceps, Via Natural or Artificial Opening
10D07Z5 Extraction of Products of Conception, High Forceps, Via Natural or Artificial Opening
10D07Z6 Extraction of Products of Conception, Vacuum, Via Natural or Artificial Opening
10D07Z7 Extraction of Products of Conception, Internal Version, Via Natural or Artificial Opening
10D07Z8 Extraction of Products of Conception, Other, Via Natural or Artificial Opening
10D17Z9 Manual Extraction of Products of Conception, Retained, Via Natural or Artificial Opening
10D18Z9 Manual Extraction of Products of Conception, Retained, Via Natural or Artificial Opening Endoscopic
10E0XZZ Delivery of Products of Conception, External Approach

Secondary diagnosis code list for outcome of delivery

Z37.0 Single live birth
Z37.1 Single stillbirth
Z37.2 Twins, both liveborn
Z37.3 Twins, one liveborn and one stillborn
Z37.4 Twins, both stillborn
Z37.50 Multiple births, unspecified, all liveborn
Z37.51 Triplets, all liveborn
Z37.52 Quadruplets, all liveborn
Z37.53 Quintuplets, all liveborn
Z37.54 Sextuplets, all liveborn
Z37.59 Other multiple births, all liveborn
Z37.60 Multiple births, unspecified, some liveborn
Z37.61 Triplets, some liveborn
Z37.62 Quadruplets, some liveborn
Z37.63 Quintuplets, some liveborn
Z37.64 Sextuplets, some liveborn
Z37.69 Other multiple births, some liveborn
Z37.7 Other multiple births, all stillborn
Z37.9 Outcome of delivery, unspecified''

We are proposing that the three ICD–10–PCS procedure codes listed in the following table would be used to establish the list of codes for the proposed Questionable Obstetric Admission edit logic for cesarean section.

ICD–10–PCS Procedure Codes for Cesarean Section Under the Proposed Questionable Obstetric Admission Edit Code List in the MCE

ICD–10–CM code	Code description
10D00Z0	Extraction of products of conception, high, open approach.
10D00Z1	Extraction of products of conception, low, open approach.
10D00Z2	Extraction of products of conception, extraperitoneal, open approach.

We are proposing that the nine ICD–10–PCS procedure codes listed in the following table would be used to establish the list of codes for the proposed new Questionable Obstetric Admission edit logic for vaginal delivery.

ICD–10–PCS PROCEDURE CODES FOR VAGINAL DELIVERY UNDER THE PROPOSED QUESTIONABLE OBSTETRIC ADMISSION EDIT CODE LIST IN THE MCE

ICD–10–CM code	Code description
10D07Z3	Extraction of products of conception, low forceps, via natural or artificial opening.
10D07Z4	Extraction of products of conception, mid forceps, via natural or artificial opening.
10D07Z5	Extraction of products of conception, high forceps, via natural or artificial opening.
10D07Z6	Extraction of products of conception, vacuum, via natural or artificial opening.
10D07Z7	Extraction of products of conception, internal version, via natural or artificial opening.
10D07Z8	Extraction of products of conception, other, via natural or artificial opening.
10D17Z9	Manual extraction of products of conception, retained, via natural or artificial opening.
10D18Z9	Manual extraction of products of conception, retained, via natural or artificial opening.
10E0XZZ	Delivery of products of conception, external approach.

We are proposing that the 19 ICD–10–CM diagnosis codes listed in the following table would be used to establish the list of secondary diagnosis codes for the proposed new Questionable Obstetric Admission edit logic for outcome of delivery.

ICD–10–CM SECONDARY DIAGNOSIS CODES FOR OUTCOME OF DELIVERY UNDER THE PROPOSED QUESTIONABLE OBSTETRIC ADMISSION EDIT CODE LIST IN THE MCE

ICD–10–CM code	Code description
Z37.0	Single live birth.
Z37.1	Single stillbirth.
Z37.2	Twins, both liveborn.
Z37.3	Twins, one liveborn and one stillborn.
Z37.4	Twins, both stillborn.
Z37.50	Multiple births, unspecified, all liveborn.
Z37.51	Triplets, all liveborn.
Z37.52	Quadruplets, all liveborn.
Z37.53	Quintuplets, all liveborn.
Z37.54	Sextuplets, all liveborn.
Z37.59	Other multiple births, all liveborn.
Z37.60	Multiple births, unspecified, some liveborn.
Z37.61	Triplets, some liveborn.
Z37.62	Quadruplets, some liveborn.
Z37.63	Quintuplets, some liveborn.
Z37.64	Sextuplets, some liveborn.
Z37.69	Other multiple births, some liveborn.
Z37.7	Other multiple births, all liveborn.
Z37.9	Outcome of delivery, unspecified.

We are inviting public comments on our proposal to create this new Questionable Obstetric Admission edit. We also are inviting public comments on the lists of diagnosis and procedure codes that we are proposing to include for this edit.

e. 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.F.9. of the preamble of this proposed rule, ICD–10–CM diagnosis codes Z49.02 (Encounter for fitting and adjustment of peritoneal dialysis catheter), Z49.31 (Encounter for adequacy testing for hemodialysis), and Z49.32 (Encounter for adequacy testing for peritoneal dialysis) are currently on the Unacceptable Principal Diagnosis edit code list. We are proposing to add diagnosis code Z49.01 (Encounter for fitting and adjustment of extracorporeal dialysis catheter) to the Unacceptable Principal Diagnosis edit code list because this is an encounter code that would more likely be performed in an outpatient setting.

As discussed in section II.F.15. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes associated with this proposed rule (which is available via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the diagnosis codes that are no longer effective as of October 1, 2018. As previously noted, included in this table is an ICD–10–CM diagnosis code Z13.4 (Encounter for screening for certain developmental disorders in childhood) which is currently listed on the Unacceptable Principal diagnoses Category edit code list. We are proposing to remove this code from the Unacceptable Principal Diagnoses Category edit code list.

We also are proposing to continue to include the other existing diagnosis codes currently listed under the Unacceptable Principal Diagnosis edit code list. We are inviting public comments on our proposals.

f. 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. We have engaged a contractor to assist in the review of the limited coverage and noncovered 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 are 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.

We have noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. 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 discussed in the FY 2018 IPPS/LTCH PPS final rule, 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 November 1, 2018 for FY 2020.

14. 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 2019 IPPS/LTCH PPS proposed rule, as discussed in section II.F.10. of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for MDC 14 (Pregnancy, Childbirth & the Puerperium) as follows: In MDC 14, we are proposing to delete MS–DRGs 765 and 766 (Cesarean Section with and without CC/MCC, respectively) and MS–DRG 767 (Vaginal Delivery with Sterilization and/or D&C) from the surgical hierarchy. We are proposing to sequence proposed new MS–DRGs 783, 784, and 785 (Cesarean Section with Sterilization with MCC, with CC and without CC/MCC, respectively) above proposed new MS–DRGs 786, 787, and 788 (Cesarean Section without Sterilization with MCC, with CC and without CC/MCC, respectively). We are proposing to sequence proposed new MS–DRGs 786, 787, and 788 (Cesarean Section without Sterilization with MCC, with CC and without CC/MCC, respectively) above MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C). We also are proposing to sequence proposed new MS–DRGs 796, 797, and 798 (Vaginal Delivery with Sterilization/D&C with MCC, with CC and without CC/MCC, respectively) below MS–DRG 768 and above MS–DRG 770 (Abortion with D&C, Aspiration Curettage or Hysterotomy). Finally, we are proposing to sequence proposed new MS–DRGs 817, 818, and 819 (Other Antepartum Diagnoses with O.R. procedure with

MCC, with CC and without CC/MCC, respectively) below MS–DRG 770 and above MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure). Our proposals for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 36 are illustrated in the following table.

PROPOSED SURGICAL HIERARCHY: MDC 14

[Pregnancy, childbirth and the puerperium]

Proposed New MS–DRGs 783–785	Cesarean Section with Sterilization.
Proposed New MS–DRGs 786–788	Cesarean Section without Sterilization.
MS–DRG 768	Vaginal Delivery with O.R. Procedures.
Proposed New MS–DRGs 796–798	Vaginal Delivery with Sterilization/D&C.
MS–DRG 770	Abortion with D&C, Aspiration Curettage or Hysterotomy.
Proposed New MS–DRGs 817–819	Other Antepartum Diagnoses with O.R. Procedure.
MS–DRG 769	Postpartum and Post Abortion Diagnoses with O.R. Procedure.

We are inviting public comments on our proposals.

As with other MS–DRG related issues, we encourage commenters to submit requests to examine ICD–10 claims pertaining to the surgical hierarchy via the CMS MS-DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2018 for FY 2020 consideration.

15. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2019

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. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2019

The following tables identifying the proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2019 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 2019;

Table 6I.2—Proposed Deletions to the MCC List—FY 2019;

Table 6J.1—Proposed Additions to the CC List—FY 2019; and

Table 6J.2—Proposed Deletions to the CC List—FY 2019.

We are inviting public comments on our proposed severity level designations for the diagnosis codes listed in Table 6I.1. and Table 6J.1. We note that, for Table 6I.2. and Table 6J.2., the proposed deletions are a result of code expansions, with the exception of diagnosis codes B20 and J80, which are the result of proposed severity level designation changes. Therefore, the diagnosis codes on these lists will no longer be valid codes, effective FY 2019.

We refer readers to the Tables 6I.1, 6I.2, 6J.1, and 6J.2 associated with this proposed rule, which are available via the Internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

c. Principal Diagnosis Is Its Own CC or MCC

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38060), we provided the public with notice of our plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38056 through 38057), we also finalized our proposal to maintain the existing lists of principal diagnosis codes in Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List for FY 2018, without any changes to the existing lists, noting our plans to conduct a comprehensive review of the CC and MCC lists for FY 2019 (82 FR 38060). We stated that having multiple lists for CC and MCC diagnoses when reported as a principal and/or secondary diagnosis may not provide an accurate representation of resource utilization for the MS–DRGs.

We also stated that the purpose of the Principal Diagnosis Is Its Own CC or MCC Lists was to ensure consistent MS–DRG assignment between the ICD–9–CM and ICD–10 MS–DRGs. The Principal Diagnosis Is Its Own CC or MCC Lists were developed for the FY 2016 implementation of the ICD–10 version of the MS–DRGs to facilitate replication of the ICD–9–CM MS–DRGs. As part of our efforts to replicate the ICD–9–CM MS–DRGs, we implemented logic that may have increased the complexity of the MS–DRG assignment hierarchy and altered the format of the ICD–10 MS–DRG Definitions Manual. Two examples of workarounds used to facilitate replication are the proliferation of procedure clusters in the surgical MS–DRGs and the creation of the Principal Diagnosis Is Its Own CC or MCC Lists special logic.

The following paragraph was added to the Version 33 ICD–10 MS–DRG Definitions Manual to explain the use of the Principal Diagnosis Is Its Own CC or MCC Lists: ''A few ICD–10–CM diagnosis codes express conditions that are normally coded in ICD–9–CM using two or more ICD–9–CM diagnosis codes. In the interest of ensuring that the ICD–10 MS–DRGs Version 33 places a patient in the same DRG regardless whether the patient record were to be coded in ICD–9–CM or ICD–10–CM/PCS, whenever one of these ICD–10–CM combination codes is used as principal diagnosis, the cluster of ICD–9–CM codes that would be coded on an ICD–9–CM record is considered. If one of the ICD–9–CM codes in the cluster is a CC

or MCC, then the single ICD–10–CM combination code used as a principal diagnosis must also imply the CC or MCC that the ICD–9–CM cluster would have presented. The ICD–10–CM diagnoses for which this implication must be made are listed here.'' Versions 34 and 35 of the ICD–10 MS–DRG Definitions Manual also include this special logic for the MS–DRGs.

The Principal Diagnosis Is Its Own CC or MCC Lists were developed in the absence of ICD–10 coded data by mapping the ICD–9–CM diagnosis codes to the new ICD–10–CM combination codes. CMS has historically used clinical judgment combined with data analysis to assign a principal diagnosis describing a complex or severe condition to the appropriate DRG or MS–DRG. The initial ICD–10 version of the MS-DRGs replicated from the ICD–9 version can now be evaluated using clinical judgment combined with ICD–10 coded data because it is no longer necessary to replicate MS–DRG assignment across the ICD–9 and ICD–10 versions of the MS–DRGs for purposes of calculating relative weights. Now that ICD–10 coded data are available, in addition to using the data for calculating relative weights, ICD–10 data can be used to evaluate the effectiveness of the special logic for assigning a severity level to a principal diagnosis, as an indicator of resource utilization. To evaluate the effectiveness of the special logic, we have conducted analysis of the ICD–10 coded data combined with clinical review to determine whether to propose to keep the special logic for assigning a severity level to a principal diagnosis, or to propose to remove the special logic and use other available means of assigning a complex principal diagnosis to the appropriate MS-DRG.

Using claims data from the September 2017 update of the FY 2017 MedPAR file, we employed the following method to determine the impact of removing the special logic used in the current Version 35 GROUPER to process claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists. Edits and cost estimations used for relative weight calculations were applied, resulting in 9,070,073 IPPS claims analyzed for this special logic impact evaluation. We refer readers to section II.G. of the preamble of this proposed rule for further information regarding the methodology for calculation of the proposed relative weights.

First, we identified the number of cases potentially impacted by the special logic. We identified 310,184 cases reporting a principal diagnosis on the Principal Diagnosis Is Its Own CC or MCC lists. Of the 310,184 total cases that reported a principal diagnosis code on the Principal Diagnosis Is Its Own CC or MCC Lists, 204,749 cases also reported a secondary diagnosis code at the same severity level or higher severity level, and therefore the special logic had no impact on MS–DRG assignment. However, of the 310,184 total cases, there were 105,435 cases that did not report a secondary diagnosis code at the same severity level or higher severity level, and therefore the special logic could potentially impact MS–DRG assignment, depending on the specific severity leveling structure of the base DRG.

Next, we removed the special logic in the GROUPER that is used for processing claims reporting a principal diagnosis on the Principal Diagnosis Is Its Own CC or MCC Lists, thereby creating a Modified Version 35 GROUPER. Using this Modified Version 35 GROUPER, we reprocessed the 105,435 claims for which the principal diagnosis code was the sole source of a MCC or CC on the case, to obtain data for comparison showing the effect of removing the special logic.

After removing the special logic in the Version 35 GROUPER for processing claims containing diagnosis codes on the Principal Diagnosis Is Its Own CC or MCC Lists, and reprocessing the claims using the Modified Version 35 GROUPER software, we found that 18,596 (6 percent) of the 310,184 cases reporting a principal diagnosis on the Principal Diagnosis Is Its Own CC or MCC Lists resulted in a different MS–DRG assignment. Overall, the number of claims impacted by removal of the special logic (18,596) represents 0.2 percent of the 9,070,073 IPPS claims analyzed.

Below we provide a summary of the steps that we followed for the analysis performed.

Step 1. We analyzed 9,070,073 claims to determine the number of cases impacted by the special logic.

WITH SPECIAL LOGIC—9,070,073 CLAIMS ANALYZED

Number of cases reporting a principal diagnosis from the Principal Diagnosis Is Its Own CC/MCC lists (special logic)	310,184
Number of cases reporting an additional CC/MCC secondary diagnosis code at or above the level of the designated severity level of the principal diagnosis	204,749
Number of cases not reporting an additional CC/MCC secondary diagnosis code	105,435

Step 2. We removed special logic from GROUPER and created a modified GROUPER.

Step 3. We reprocessed 105,435 claims with modified GROUPER.

WITHOUT SPECIAL LOGIC—105,435 CLAIMS ANALYZED

Number of cases reporting a principal diagnosis from the Principal Diagnosis Is Its Own CC/MCC lists	310,184
Number of cases resulting in different MS–DRG assignment	18,596

To estimate the overall financial impact of removing the special logic from the GROUPER, we calculated the aggregate change in estimated payment for the MS–DRGs by comparing average costs for each MS–DRG affected by the change, before and after removing the special logic. Before removing the special logic in the Version 35 GROUPER, the cases impacted by the special logic had an estimated average payment of $58 million above the average costs for all the MS–DRGs to which the claim was originally assigned. After removing the special logic in the Version 35 GROUPER, the 18,596 cases impacted by the special logic had an estimated average payment of $39 million below the average costs for the newly assigned MS–DRGs.

We performed regression analysis to compare the proportion of variance in the MS–DRGs with and without the special logic. The results of the

regression analysis showed a slight decrease in variance when the logic was removed. While the decrease itself was not statistically significant (an R-squared of 36.2603 percent after the special logic was removed, compared with an R-squared of 36.2501 percent in the current version 35 GROUPER), we note that the proportion of variance across the MS–DRGs essentially stayed the same, and certainly did not increase, when the special logic was removed.

We further examined the 18,596 claims that were impacted by the special logic in the GROUPER for processing claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists. The 18,596 claims were analyzed by the principal diagnosis code and the MS–DRG assigned, resulting in 588 principal diagnosis and MS–DRG combinations or subsets. Of the 588 subsets of cases that utilized the special logic, 556 of the 588 subsets (95 percent) had fewer than 100 cases, 529 of the 588 subsets (90 percent) had fewer than 50 cases, and 489 of the 588 subsets (83 percent) had fewer than 25 cases.

We examined the 32 subsets of cases (5 percent of the 588 subsets) that utilized the special logic and had 100 or more cases. Of the 32 subsets of cases, 18 (56 percent) are similar in terms of average costs and length of stay to the MS–DRG assignment that results when the special logic is removed, and 14 of the 32 subsets of cases (44 percent) are similar in terms of average costs and length of stay to the MS–DRG assignment that results when the special logic is utilized.

The table below contains examples of four subsets of cases that utilize the special logic, comparing average length of stay and average costs between two MS–DRGs within a base DRG, corresponding to the MS–DRG assigned when the special logic is removed and the MS–DRG assigned when the special logic is utilized. All four subsets of cases involve the principal diagnosis code E11.52 (Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene). There are four subsets of cases in this example because the records involving the principal diagnosis code E11.52 are assigned to four different base DRGs, one medical MS–DRG and three surgical MS-DRGs, depending on the procedure code(s) reported on the claim. All subsets of cases contain more than 100 claims. In three of the four subsets, the cases are similar in terms of average length of stay and average costs to the MS–DRG assignment that results when the special logic is removed, and in one of the four subsets, the cases are similar in terms of average length of stay and average costs to the MS–DRG assignment that results when the special logic is utilized.

As shown in the following table, using ICD–10–CM diagnosis code E11.52 (Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene) as our example, the data findings show four different MS–DRG pairs for which code E11.52 was the principal diagnosis on the claim and where the special logic impacted MS–DRG assignment. For the first MS–DRG pair, we examined MS–DRGs 240 and 241 (Amputation for Circulatory System Disorders Except Upper Limb and Toe with CC and without CC/MCC, respectively). We found 436 cases reporting diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 5.5 days and average costs of $11,769. These 436 cases are assigned to MS–DRG 240 with the special logic utilized, and assigned to MS–DRG 241 with the special logic removed. The total number of cases reported in MS–DRG 240 was 7,675, with an average length of stay of 8.3 days and average costs of $17,876. The total number of cases reported in MS–DRG 241 was 778, with an average length of stay of 5.0 days and average costs of $10,882. The 436 cases are more similar to MS–DRG 241 in terms of length of stay and average cost and less similar to MS–DRG 240.

For the second MS–DRG pair, we examined MS–DRGs 256 and 257 (Upper Limb and Toe Amputation for Circulatory System Disorders with CC and without CC/MCC, respectively). We found 193 cases reporting ICD–10–CM diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 4.2 days and average costs of $8,478. These 193 cases are assigned to MS–DRG 256 with the special logic utilized, and assigned to MS–DRG 257 with the special logic removed. The total number of cases reported in MS–DRG 256 was 2,251, with an average length of stay of 6.1 days and average costs of $11,987. The total number of cases reported in MS–DRG 257 was 115, with an average length of stay of 4.6 days and average costs of $7,794. These 193 cases are more similar to MS–DRG 257 in terms of average length of stay and average costs and less similar to MS–DRG 256.

For the third MS–DRG pair, we examined MS–DRGs 300 and 301 (Peripheral Vascular Disorders with CC and without CC/MCC, respectively). We found 185 cases reporting ICD–10–CM diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 3.6 days and average costs of $5,981. These 185 cases are assigned to MS–DRG 300 with the special logic utilized, and assigned to MS–DRG 301 with the special logic removed. The total number of cases reported in MS–DRG 300 was 29,327, with an average length of stay of 4.1 days and average costs of $7,272. The total number of cases reported in MS–DRG 301 was 9,611, with an average length of stay of 2.8 days and average costs of $5,263. These 185 cases are more similar to MS–DRG 301 in terms of average length of stay and average costs and less similar to MS–DRG 300.

For the fourth MS–DRG pair, we examined MS–DRGs 253 and 254 (Other Vascular Procedures with CC and without CC/MCC, respectively). We found 225 cases reporting diagnosis code E11.52 as the principal diagnosis, with an average length of stay of 5.2 days and average costs of $17,901. These 225 cases are assigned to MS–DRG 253 with the special logic utilized, and assigned to MS–DRG 254 with the special logic removed. The total number of cases reported in MS–DRG 253 was 25,714, with an average length of stay of 5.4 days and average costs of $18,986. The total number of cases reported in MS–DRG 254 was 12,344, with an average length of stay of 2.8 days and average costs of $13,287. Unlike the previous three MS–DRG pairs, these 225 cases are more similar to MS–DRG 253 in terms of average length of stay and average costs and less similar to MS–DRG 254.

MS–DRG Pairs for Principal Diagnosis ICD–10–CM Code E11.52 With and Without Special MS–DRG Logic

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 240 and 241—Special logic impacted cases with ICD–10–CM code E11.52 as principal diagnosis	436	5.5	$11,769
MS–DRG 240—All cases	7,675	8.3	17,876
MS–DRG 241—All cases	778	5.0	10,882

MS–DRG PAIRS FOR PRINCIPAL DIAGNOSIS ICD–10–CM CODE E11.52 WITH AND WITHOUT SPECIAL MS–DRG LOGIC—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 253 and 254—Special logic impacted cases with ICD–10–CM E11.52 as principal diagnosis	225	5.2	17,901
MS–DRG 253—All cases	25,714	5.4	18,986
MS–DRG 254—All cases	12,344	2.8	13,287
MS–DRGs 256 and 257—Special logic impacted cases with ICD–10–CM E11.52 as principal diagnosis	193	4.2	8,478
MS–DRG 256—All cases	2,251	6.1	11,987
MS–DRG 257—All cases	115	4.6	7,794
MS–DRGs 300 and 301—Special logic impacted cases with ICD–10–CM E11.52 as principal diagnosis	185	3.6	5,981
MS–DRG 300—All cases	29,327	4.1	7,272
MS–DRG 301—All cases	9,611	2.8	5,263

Based on our analysis of the data, we believe that there may be more effective indicators of resource utilization than the Principal Diagnosis Is Its Own CC or MCC Lists and the special logic used to assign clinical severity to a principal diagnosis. As stated earlier in this discussion, it is no longer necessary to replicate MS–DRG assignment across the ICD–9 and ICD–10 versions of the MS–DRGs. The available ICD–10 data can now be used to evaluate other indicators of resource utilization.

Therefore, as an initial recommendation from the first phase in our comprehensive review of the CC and MCC lists, we are proposing to remove the special logic in the GROUPER for processing claims containing a diagnosis code from the Principal Diagnosis Is Its Own CC or MCC Lists, and we are proposing to delete the tables containing the lists of principal diagnosis codes, Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List, from the ICD–10 MS–DRG Definitions Manual for FY 2019. We are inviting public comments on our proposals.

d. Proposed CC Exclusions List for FY 2019

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.

In this proposed rule, for FY 2019, we are proposing changes to the ICD–10 MS–DRGs Version 36 CC Exclusion List. Therefore, we developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2019; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2019; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2019; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2019. 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.*

To identify new, revised and deleted diagnosis and procedure codes, for FY 2019, we developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this proposed rule.

These tables are not published in the Addendum to the 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.F.18. 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 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.

In this FY 2019 IPPS/LTCH PPS proposed rule, we are inviting public comments on the MDC and MS–DRG assignments for the new diagnosis and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, we are inviting public comments on the proposed severity level designations for the new diagnosis codes as set forth in Table 6A. and the proposed O.R. status for the new procedure codes as 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 2019;
- Table 6B.—New Procedure Codes—FY 2019;
- Table 6C.—Invalid Diagnosis Codes—FY 2019;
- Table 6D.—Invalid Procedure Codes—FY 2019;
- Table 6E.—Revised Diagnosis Code Titles—FY 2019;
- Table 6F.—Revised Procedure Code Titles—FY 2019;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2019;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2019;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2019;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2019;
- Table 6I.1.—Proposed Additions to the MCC List—FY 2019;
- Table 6I.2.—Proposed Deletions to the MCC List—FY 2019;
- Table 6J.1.—Proposed Additions to the CC List—FY 2019; and
- Table 6J.2.—Proposed Deletions to the CC List—FY 2019.

We note that, as discussed in section II.F.15.c. of the preamble of this proposed rule, we are proposing to delete Table 6L. and Table 6M. from the ICD–10 MS–DRG Definitions Manual for FY 2019.

16. Comprehensive Review of CC List for FY 2019

a. 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 an MCC, CC, or 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 this 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. However, given the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since this review, we believe it is necessary to conduct a comprehensive analysis once again. We have begun this analysis and will discuss our findings in future rulemaking. We are currently using the same methodology utilized in FY 2008 and described below to conduct this analysis.

For each secondary diagnosis, we measured the impact in resource use for the following three subsets of patients:

(1) Patients with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs.

(2) Patients with at least one other secondary diagnosis that is a CC but none that is an MCC.

(3) Patients with at least one other secondary diagnosis that is an MCC.

Numerical resource impact values were assigned for each diagnosis as follows:

Value	Meaning
0	Significantly below expected value for the non-CC subgroup.
1	Approximately equal to expected value for the non-CC subgroup.
2	Approximately equal to expected value for the CC subgroup.
3	Approximately equal to expected value for the MCC subgroup.
4	Significantly above the expected value for the MCC subgroup.

Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset and C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a major CC. The C3 value reflects a patient with at least one other secondary diagnosis that is a major CC. A value close to 1.0 in the C1 field would suggest that the code produces the same expected value as a non-CC diagnosis. That is, average costs for the case are similar to the expected average costs for that subset and the diagnosis is not expected to increase resource usage. A higher value in the C1 (or C2 and C3) field suggests more resource usage is associated with the diagnosis and an increased likelihood that it is more like a CC or major CC than a non-CC. Thus, a value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For example, a C1 value of 1.8 for a secondary diagnosis means that for the subset of patients who have the secondary diagnosis and have either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs, the impact on resource use of the secondary diagnoses is greater than the expected value for a non-CC by an amount equal to 80

percent of the difference between the expected value of a CC and a non-CC (that is, the impact on resource use of the secondary diagnosis is closer to a CC than a non-CC).

These mathematical constructs are used as guides in conjunction with the judgment of our clinical advisors to classify each secondary diagnosis reviewed as an MCC, CC or non-CC. Our clinical panel reviews the resource use impact reports and suggests modifications to the initial CC subclass assignments when clinically appropriate.

b. Requested Changes to Severity Levels

(1) Human Immunodeficiency Virus [HIV] Disease

We received a request that we consider changing the severity level of ICD–10–CM diagnosis code B20 (Human immunodeficiency virus [HIV] disease) from an MCC to a CC. We used the approach outlined above to evaluate this request. The table below contains the data that were evaluated for this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
B20 (Human immunodeficiency virus [HIV] disease)	2,918	0.9946	8,938	2.1237	11,479	3.0960	MCC	CC

While the data did not strongly suggest that the categorization of HIV as an MCC was inaccurate, our clinical advisors indicated that, for many patients with HIV disease, symptoms are well controlled by medications. Our clinical advisors stated that if these patients have an HIV-related complicating disease, that complicating disease would serve as a CC or an MCC. Therefore, they advised us that ICD–10–CM diagnosis code B20 is more similar to a CC than an MCC. Based on the data results and the advice of our clinical advisors, we are proposing to change the severity level of ICD–10–CM diagnosis code B20 from an MCC to a CC. We are inviting public comments on our proposal.

(2) Acute Respiratory Distress Syndrome

We also received a request to change the severity level for ICD–10–CM diagnosis code J80 (Acute respiratory distress syndrome) from a CC to a MCC. We used the approach outlined above to evaluate this request. The following table contains the data that were evaluated for this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
J80 (Acute respiratory distress syndrome)	1,840	1.7704	6,818	2.5596	18,376	3.3428	CC	MCC

The data suggest that the resources involved in caring for a patient with this condition are 77 percent greater than expected when the patient has either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs. The resources are 56 percent greater than expected when reported in conjunction with another secondary diagnosis that is a CC, and 34 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. Our clinical advisors agree that the resources required to care for a patient with this secondary diagnosis are consistent with those of an MCC. Therefore, we are proposing to change the severity level of ICD–10–CM diagnosis code J80 from a CC to an MCC. We are inviting public comments on our proposal.

(3) Encephalopathy

We also received a request to change the severity level for ICD–10–CM diagnosis code G93.40 (Encephalopathy, unspecified) from an MCC to a non-CC. The requestor pointed out that the nature of the encephalopathy or its underlying cause should be coded. The requestor also noted that unspecified heart failure is a non-CC. We used the approach outlined earlier to evaluate this request. The following table contains the data that were evaluated for this request.

ICD–10–CM diagnosis code	Cnt1	C1	Cnt2	C2	Cnt3	C3	Current CC subclass	Proposed CC subclass
G93.40 (Encephalopathy, unspecified)	1.840	16,306	1.8471	80,222	2.4901	139,066	MCC	MCC

The data suggest that the resources involved in caring for a patient with this condition are 84 percent greater than expected when the patient has either no other secondary diagnosis present, or all the other secondary diagnoses present are non-CCs. The resources are 15 percent lower than expected when reported in conjunction with another secondary diagnosis that is a CC, and 49 percent greater than expected when reported in conjunction with another secondary diagnosis code that is an MCC. We note that the pattern observed in resource use for the condition of unspecified heart failure (ICD–10–CM diagnosis code I50.9) differs from that of unspecified encephalopathy. Our clinical advisors reviewed this request and agree that the resources involved in caring for a patient with this condition are aligned with those of an MCC. Therefore, we are not proposing a change to the severity level for ICD–10–CM diagnosis code G93.40. We are inviting public comments on our proposal.

17. Review of Procedure Codes in MS DRGs 981 Through 983 and 987 Through 989

Each year, we review cases 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) and MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS–DRGs. MS–DRGs 981 through 983 and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

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 (Nonextensive 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 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 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. Based on the results of our review of the claims data from the September 2017 update of the FY 2017 MedPAR file, we are not proposing to move any procedures 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 is assigned. We are inviting public comments on our proposal to maintain the current structure of these MS–DRGs.

b. 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 the September 2017 update of the FY 2017 MedPAR file, we are proposing to maintain the current structure of MS–DRGs 981 through 983 and MS–DRGs 987 through 989.

We are inviting public comments on our proposal.

c. Adding Diagnosis or Procedure Codes to MDCs

We received a request recommending that CMS reassign cases for congenital pectus excavatum (congenital depression of the sternum or concave chest) when reported with a procedure describing repositioning of the sternum (the Nuss procedure) 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). ICD–10–CM diagnosis code Q67.6 (Pectus excavatum) is reported for this congenital condition and is currently assigned to MDC 4 (Diseases and Disorders of the Respiratory System). ICD–10–PCS procedure code 0PS044Z (Reposition sternum with internal fixation device, percutaneous endoscopic approach) may be reported to identify the Nuss procedure and is currently assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517. The requester noted that *acquired* pectus excavatum (ICD–10–CM diagnosis code M95.4) groups to MS–DRGs 515, 516, and 517 when reported with a ICD–10–PCS procedure code describing repositioning of the sternum and requested that cases involving diagnoses describing *congenital* pectus excavatum also group to those MS–DRGs when reported with a ICD–10–PCS procedure code describing repositioning of the sternum.

Our analysis of this grouping issue confirmed that, when pectus excavatum (ICD–10–CM diagnosis code Q67.6) is reported as a principal diagnosis with a procedure such as the Nuss procedure (ICD–10–PCS procedure code 0PS044Z), 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, which 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.'' In the example provided, because the ICD–10–CM diagnosis code Q67.6 describing pectus excavatum is classified to MDC 4 and the ICD–10–PCS procedure code 0PS044Z is classified to MDC 8, the GROUPER logic assigns this case to the ''unrelated operating room procedures'' set of MS–DRGs.

During our review of ICD–10–CM diagnosis code Q67.6, we also reviewed additional ICD–10–CM diagnosis codes in the Q65 through Q79 code range to determine if there might be other conditions classified to MDC 4 that describe congenital malformations and deformities of the musculoskeletal system. We identified the following six ICD–10–CM diagnosis codes:

ICD–10–CM code	Code description
Q67.7	Pectus carinatum.
Q76.6	Other congenital malformations of ribs.
Q76.7	Congenital malformation of sternum.
Q76.8	Other congenital malformations of bony thorax.
Q76.9	Congenital malformation of bony thorax, unspecified.
Q77.2	Short rib syndrome.

We are proposing to reassign ICD–10–CM diagnosis code Q67.6, as well as the additional six ICD–10–CM diagnosis codes above describing congenital musculoskeletal conditions, from MDC 4 to MDC 8 where other related congenital conditions that correspond to the musculoskeletal system are classified, as discussed further below.

We identified other related ICD–10–CM diagnosis codes that are currently assigned to MDC 8 in categories Q67 (Congenital musculoskeletal deformities of head, face, spine and chest), Q76 (Congenital malformations of spine and bony thorax), and Q77 (Osteochondrodysplasia with defects of growth of tubular bones and spine) that are listed in the following table.

ICD–10–CM code	Code description
Q67.0	Congenital facial asymmetry.
Q67.1	Congenital compression facies.
Q67.2	Dolichocephaly.
Q67.3	Plagiocephaly.
Q67.4	Other congenital deformities of skull, face and jaw.
Q67.5	Congenital deformity of spine.
Q67.8	Other congenital deformities of chest.
Q76.1	Klippel-Feil syndrome.
Q76.2	Congenital spondylolisthesis.
Q76.3	Congenital scoliosis due to congenital bony malformation.
Q76.411	Congenital kyphosis, occipito-atlanto-axial region.
Q76.412	Congenital kyphosis, cervical region.
Q76.413	Congenital kyphosis, cervicothoracic region.
Q76.414	Congenital kyphosis, thoracic region.
Q76.415	Congenital kyphosis, thoracolumbar region.
Q76.419	Congenital kyphosis, unspecified region.
Q76.425	Congenital lordosis, thoracolumbar region.
Q76.426	Congenital lordosis, lumbar region.
Q76.427	Congenital lordosis, lumbosacral region.
Q76.428	Congenital lordosis, sacral and sacrococcygeal region.
Q76.429	Congenital lordosis, unspecified region.
Q76.49	Other congenital malformations of spine, not associated with scoliosis.
Q76.5	Cervical rib.
Q77.0	Achondrogenesis.
Q77.1	Thanatophoric short stature.
Q77.3	Chondrodysplasia punctate.
Q77.4	Achondroplasia.
Q77.5	Diastrophic dysplasia.
Q77.6	Chondroectodermal dysplasia.
Q77.7	Spondyloepiphyseal dysplasia.
Q77.8	Other osteochondrodysplasia with defects of growth of tubular bones and spine.
Q77.9	Osteochondrodysplasia with defects of growth of tubular bones and spine, unspecified.

Next, we analyzed the MS–DRG assignments for the related codes listed above and found that cases with the following conditions are assigned to MS–DRGs 551 and 552 (Medical Back Problems with and without MCC, respectively) under MDC 8.

ICD–10–CM code	Code description
Q76.2	Congenital spondylolisthesis.
Q76.411	Congenital kyphosis, occipito-atlanto-axial region.
Q76.412	Congenital kyphosis, cervical region.
Q76.413	Congenital kyphosis, cervicothoracic region.
Q76.414	Congenital kyphosis, thoracic region.
Q76.415	Congenital kyphosis, thoracolumbar region.
Q76.419	Congenital kyphosis, unspecified region.
Q76.49	Other congenital malformations of spine, not associated with scoliosis.

The remaining conditions shown below are assigned to MS–DRGs 564, 565, and 566 (Other Musculoskeletal System and Connective Tissue Diagnoses with MCC, with CC, and without CC/MCC, respectively) under MDC 8.

ICD–10–CM code	Code description
Q67.0	Congenital facial asymmetry.
Q67.1	Congenital compression facies.
Q67.2	Dolichocephaly.
Q67.3	Plagiocephaly.

ICD–10–CM code	Code description
Q67.4	Other congenital deformities of skull, face and jaw.
Q67.5	Congenital deformity of spine.
Q67.8	Other congenital deformities of chest.
Q76.1	Klippel-Feil syndrome.
Q76.3	Congenital scoliosis due to congenital bony malformation.
Q76.425	Congenital lordosis, thoracolumbar region.
Q76.426	Congenital lordosis, lumbar region.
Q76.427	Congenital lordosis, lumbosacral region.
Q76.428	Congenital lordosis, sacral and sacrococcygeal region.
Q76.429	Congenital lordosis, unspecified region.
Q76.5	Cervical rib.
Q77.0	Achondrogenesis.
Q77.1	Thanatophoric short stature.
Q77.3	Chondrodysplasia punctate.
Q77.4	Achondroplasia.
Q77.5	Diastrophic dysplasia.
Q77.6	Chondroectodermal dysplasia.
Q77.7	Spondyloepiphyseal dysplasia.
Q77.8	Other osteochondrodysplasia with defects of growth of tubular bones and spine.
Q77.9	Osteochondrodysplasia with defects of growth of tubular bones and spine, unspecified.

As a result of our review, we are proposing to reassign ICD–10–CM diagnosis code Q67.6, as well as the additional six ICD–10–CM diagnosis codes above describing congenital musculoskeletal conditions, from MDC 4 to MDC 8 in MS–DRGs 564, 565, and 566. Our clinical advisors agree with this proposed reassignment because it is clinically appropriate and consistent with the other related ICD–10–CM diagnosis codes grouped in the Q65 through Q79 range that describe congenital malformations and deformities of the musculoskeletal system that are classified under MDC 8 in MS–DRGs 564, 565, and 566. By reassigning ICD–10–CM diagnosis code Q67.6 and the additional six ICD–10–CM diagnosis codes listed in the table above from MDC 4 to MDC 8, cases reporting these ICD–10–CM diagnosis codes in combination with the respective ICD–10–PCS procedure code will reflect a more appropriate grouping from a clinical perspective because they will now be classified under a surgical musculoskeletal system related MS–DRG and will no longer result in an MS–DRG assignment to the ''unrelated operating room procedures'' surgical class.

In summary, we are proposing to reassign ICD–10–CM diagnosis codes Q67.6, Q67.7, Q76.6, Q76.7, Q76.8, Q76.9, and Q77.2 from MDC 4 to MDC 8 in MS–DRGs 564, 565, and 566 (Other Musculoskeletal System and Connective Tissue Diagnoses with MCC, with CC, and without CC/MCC, respectively). We are inviting public comments on our proposals.

We also received a request recommending that CMS reassign cases for sternal fracture repair procedures from MS–DRGs 981, 982, and 983 and from MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively) under MDC 4 to MS–DRGs 515, 516, and 517 under MDC 8. The requester noted that clavicle fracture repair procedures with an internal fixation device group to MS–DRGs 515, 516, and 517 when reported with an ICD–10–CM diagnosis code describing a fractured clavicle. However, sternal fracture repair procedures with an internal fixation device group to MS–DRGs 981, 982, and 983 or MS–DRGs 166, 167 and 168 when reported with an ICD–10–CM diagnosis code describing a fracture of the sternum. According to the requestor, because the clavicle and sternum are in the same anatomical region of the body, it would appear that assignment to MS–DRGs 515, 516, and 517 would be more appropriate for sternal fracture repair procedures.

The requestor provided the following list of ICD–10–PCS procedure codes in its request for consideration to reassign to MS–DRGs 515, 516 and 517 when reported with an ICD–10–CM diagnosis code for sternal fracture.

ICD–10–PCS code	Code description
0PS000Z	Reposition sternum with rigid plate internal fixation device, open approach.
0PS004Z	Reposition sternum with internal fixation device, open approach.
0PS00ZZ	Reposition sternum, open approach.
0PS030Z	Reposition sternum with rigid plate internal fixation device, percutaneous approach.
0PS034Z	Reposition sternum with internal fixation device, percutaneous approach.

We note that the above five ICD–10–PCS procedure codes that may be reported to describe a sternal fracture repair are already assigned to MS–DRGs 515, 516, and 517 under MDC 8. In addition, ICD–10–PCS procedure codes 0PS000Z and 0PS030Z are assigned to MS–DRGs 166, 167 and 168 under MDC 4.

As noted in the previous discussion, whenever there is a surgical procedure reported on a claim, which 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.'' In the examples provided by the requestor, when the ICD–10–CM diagnosis code describing a sternal fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a sternal fracture repair procedure is classified under MDC 8, the GROUPER logic assigns these cases to the ''unrelated operating room procedures'' group of MS–DRGs (981,

982, and 983) and when the ICD–10–CM diagnosis code describing a sternal fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a sternal repair procedure is also classified under MDC 4, the GROUPER logic assigns these cases to MS–DRG 166, 167, or 168.

For our review of this grouping issue and the request to have procedures for sternal fracture repairs assigned to MDC 8, we analyzed the ICD–10–CM diagnosis codes describing a sternal fracture currently classified under MDC 4. We identified 10 ICD–10–CM diagnosis codes describing a sternal fracture with an ''initial encounter'' classified under MDC 4 that are listed in the following table.

ICD–10–CM code	Code description
S22.20XA	Unspecified fracture of sternum, initial encounter for closed fracture.
S22.20XB	Unspecified fracture of sternum, initial encounter for open fracture.
S22.21XA	Fracture of manubrium, initial encounter for closed fracture.
S22.21XB	Fracture of manubrium, initial encounter for open fracture.
S22.22XA	Fracture of body of sternum, initial encounter for closed fracture.
S22.22XB	Fracture of body of sternum, initial encounter for open fracture.
S22.23XA	Sternal manubrial dissociation, initial encounter for closed fracture.
S22.23XB	Sternal manubrial dissociation, initial encounter for open fracture.
S22.24XA	Fracture of xiphoid process, initial encounter for closed fracture.
S22.24XB	Fracture of xiphoid process, initial encounter for open fracture.

Our analysis of this grouping issue confirmed that when 1 of the 10 ICD–10–CM diagnosis codes describing a sternal fracture listed in the table above from MDC 4 is reported as a principal diagnosis with an ICD–10–PCS procedure code for a sternal repair procedure from MDC 8, these cases group to MS–DRG 981, 982, or 983. We also confirmed that when 1 of the 10 ICD–10–CM diagnosis codes describing a sternal fracture listed in the table above from MDC 4 is reported as a principal diagnosis with an ICD–10–PCS procedure code for a sternal repair procedure from MDC 4, these cases group to MS–DRG 166, 167 or 168.

Our clinical advisors agree with the requested reclassification of ICD–10–CM diagnosis codes S22.20XA, S22.20XB, S22.21XA, S22.21XB, S22.22XA, S22.22XB, S22.23XA, S22.23XB, S22.24XA, and S22.24XB describing a sternal fracture with an initial encounter from MDC 4 to MDC 8. They advised that this requested reclassification is clinically appropriate because it is consistent with the other related ICD–10–CM diagnosis codes that describe fractures of the sternum and which are classified under MDC 8. The ICD–10–CM diagnosis codes describing a sternal fracture currently classified under MDC 8 to MS–DRGs 564, 565, and 566 are listed in the following table.

ICD–10–CM code	Code description
S22.20XD	Unspecified fracture of sternum, subsequent encounter for fracture with routine healing.
S22.20XG	Unspecified fracture of sternum, subsequent encounter for fracture with delayed healing.
S22.20XK	Unspecified fracture of sternum, subsequent encounter for fracture with nonunion.
S22.20XS	Unspecified fracture of sternum, sequela.
S22.21XD	Fracture of manubrium, subsequent encounter for fracture with routine healing.
S22.21XG	Fracture of manubrium, subsequent encounter for fracture with delayed healing.
S22.21XK	Fracture of manubrium, subsequent encounter for fracture with nonunion.
S22.21XS	Fracture of manubrium, sequela.
S22.22XD	Fracture of body of sternum, subsequent encounter for fracture with routine healing.
S22.22XG	Fracture of body of sternum, subsequent encounter for fracture with delayed healing.
S22.22XK	Fracture of body of sternum, subsequent encounter for fracture with nonunion.
S22.22XS	Fracture of body of sternum, sequela.
S22.23XD	Sternal manubrial dissociation, subsequent encounter for fracture with routine healing.
S22.23XG	Sternal manubrial dissociation, subsequent encounter for fracture with delayed healing.
S22.23XK	Sternal manubrial dissociation, subsequent encounter for fracture with nonunion.
S22.23XS	Sternal manubrial dissociation, sequela.
S22.24XD	Fracture of xiphoid process, subsequent encounter for fracture with routine healing.
S22.24XG	Fracture of xiphoid process, subsequent encounter for fracture with delayed healing.
S22.24XK	Fracture of xiphoid process, subsequent encounter for fracture with nonunion.
S22.24XS	Fracture of xiphoid process, sequela.

By reclassifying the 10 ICD–10–CM diagnosis codes listed in the table earlier in this section describing sternal fracture codes with an ''initial encounter'' from MDC 4 to MDC 8, the cases reporting these ICD–10–CM diagnosis codes in combination with the respective ICD–10–PCS procedure codes will reflect a more appropriate grouping from a clinical perspective and will no longer result in an MS–DRG assignment to the ''unrelated operating room procedures'' surgical class when reported with a surgical procedure classified under MDC 8.

Therefore, we are proposing to reassign ICD–10–CM diagnosis codes S22.20XA, S22.20XB, S22.21XA, S22.21XB, S22.22XA, S22.22XB, S22.23XA, S22.23XB, S22.24XA, and S22.24XB from under MDC 4 to MDC 8 to MS–DRGs 564, 565, and 566. We are inviting public comments on our proposals.

In addition, we received a request recommending that CMS reassign cases for rib fracture repair procedures from MS–DRGs 981, 982, and 983, and from MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures

with MCC, with CC, and without CC/MCC, respectively) under MDC 4 to MS–DRGs 515, 516, and 517 under MDC 8. The requestor noted that clavicle fracture repair procedures with an internal fixation device group to MS–DRGs 515, 516, and 517 when reported with an ICD–10–CM diagnosis code describing a fractured clavicle. However, rib fracture repair procedures with an internal fixation device group to MS–DRGs 981, 982, and 983 or to MS–DRGs 166, 167 and 168 when reported with an ICD–10–CM diagnosis code describing a rib fracture. According to the requestor, because the clavicle and ribs are in the same anatomical region of the body, it would appear that assignment to MS–DRGs 515, 516, and 517 would be more appropriate for rib fracture repair procedures.

The requestor provided the following list of 10 ICD–10–PCS procedure codes in its request for consideration for reassignment to MS–DRGs 515, 516 and 517 when reported with an ICD–10–CM diagnosis code for rib fracture.

ICD–10–PCS code	Code description
0PH104Z	Insertion of internal fixation device into 1 to 2 ribs, open approach.
0PH134Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous approach.
0PH144Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous endoscopic approach.
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach.
0PH234Z	Insertion of internal fixation device into 3 or more ribs, percutaneous approach.
0PH244Z	Insertion of internal fixation device into 3 or more ribs, percutaneous endoscopic approach.
0PS104Z	Reposition 1 to 2 ribs with internal fixation device, open approach.
0PS134Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous approach.
0PS204Z	Reposition 3 or more ribs with internal fixation, device, open approach.
0PS234Z	Reposition 3 or more ribs with internal fixation device, percutaneous approach.

We note that the above 10 ICD–10–PCS procedure codes that may be reported to describe a rib fracture repair are already assigned to MS–DRGs 515, 516, and 517 under MDC 8. In addition, 6 of the 10 ICD 10–PCS procedure codes listed above (0PH104Z, 0PH134Z, 0PH144Z, 0PH204Z, 0PH234Z and 0PH244Z) are also assigned to MS–DRGs 166, 167, and 168 under MDC 4.

As noted in the previous discussions above, whenever there is a surgical procedure reported on a claim, which 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.'' In the examples provided by the requestor, when the ICD–10–CM diagnosis code describing a rib fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a rib fracture repair procedure is classified under MDC 8, the GROUPER logic assigns these cases to the ''unrelated operating room procedures'' group of MS–DRGs (981, 982, and 983) and when the ICD–10–CM diagnosis code describing a rib fracture is classified under MDC 4 and the ICD–10–PCS procedure code describing a rib repair procedure is also classified under MDC 4, the GROUPER logic assigns these cases to MS–DRG 166, 167, or 168.

For our review of this grouping issue and the request to have procedures for rib fracture repairs assigned to MDC 8, we analyzed the ICD–10–CM diagnosis codes describing a rib fracture and found that, while some rib fracture ICD–10–CM diagnosis codes are classified under MDC 8 (which would result in those cases grouping appropriately to MS–DRGs 515, 516, and 517), there are other ICD–10–CM diagnosis codes that are currently classified under MDC 4. We identified the following ICD–10–CM diagnosis codes describing a rib fracture with an initial encounter classified under MDC 4, as listed in the following table.

ICD–10–PCS code	Code description
S2231XA	Fracture of one rib, right side, initial encounter for closed fracture.
S2231XB	Fracture of one rib, right side, initial encounter for open fracture.
S2232XA	Fracture of one rib, left side, initial encounter for closed fracture.
S2232XB	Fracture of one rib, left side, initial encounter for open fracture.
S2239XA	Fracture of one rib, unspecified side, initial encounter for closed fracture.
S2239XB	Fracture of one rib, unspecified side, initial encounter for open fracture.
S2241XA	Multiple fractures of ribs, right side, initial encounter for closed fracture.
S2241XB	Multiple fractures of ribs, right side, initial encounter for open fracture.
S2242XA	Multiple fractures of ribs, left side, initial encounter for closed fracture.
S2242XB	Multiple fractures of ribs, left side, initial encounter for open fracture.
S2243XA	Multiple fractures of ribs, bilateral, initial encounter for closed fracture.
S2243XB	Multiple fractures of ribs, bilateral, initial encounter for open fracture.
S2249XA	Multiple fractures of ribs, unspecified side, initial encounter for closed fracture.
S2249XB	Multiple fractures of ribs, unspecified side, initial encounter for open fracture.
S225XXA	Flail chest, initial encounter for closed fracture.
S225XXB	Flail chest, initial encounter for open fracture.

Our analysis of this grouping issue confirmed that, when one of the following four ICD–10–PCS procedure codes identified by the requestor (and listed in the table earlier in this section) from MDC 8 (0PS104Z, 0PS134Z, 0PS204Z, or 0PS234Z) is reported to describe a rib fracture repair procedure with a principal diagnosis code for a rib fracture with an initial encounter listed in the table above from MDC 4, these cases group to MS–DRG 981, 982, or 983.

During our review of those four repositioning of the rib procedure codes, we also identified the following four ICD–10–PCS procedure codes classified

to MDC 8 that describe repositioning of the ribs.

ICD–10–PCS code	Code description
0PS10ZZ	Reposition 1 to 2 ribs, open approach.
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach.
0PS20ZZ	Reposition 3 or more ribs, open approach.
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach.

We confirmed that when one of the above four procedure codes is reported with a principal diagnosis code for a rib fracture listed in the table above from MDC 4, these cases also group to MS–DRG 981, 982, or 983.

Lastly, we confirmed that when one of the six ICD–10–PCS procedure codes describing a rib fracture repair listed in the previous table above from MDC 4 is reported with a principal diagnosis code for a rib fracture with an initial encounter from MDC 4, these cases group to MS–DRG 166, 167, or 168.

In response to the request to reassign the procedure codes that describe a rib fracture repair procedure from MS–DRGs 981, 982, and 983 and from MS–DRGs 166, 167, and 168 under MDC 4 to MS–DRGs 515, 516, and 517 under MDC 8, as discussed above, the 10 ICD–10–PCS procedure codes submitted by the requestor that may be reported to describe a rib fracture repair are already assigned to MS–DRGs 515, 516, and 517 under MDC 8 and 6 of those 10 procedure codes (0PH104Z, 0PH134Z, 0PH144Z, 0PH204Z, 0PH234Z, and 0PH244Z) are also assigned to MS–DRGs 166, 167, and 168 under MDC 4.

We analyzed claims data from the September 2017 update of the FY 2017 MedPAR file for cases reporting a principal diagnosis of a rib fracture (initial encounter) from the list of diagnosis codes shown in the table above with one of the six ICD–10–PCS procedure codes describing the insertion of an internal fixation device into the rib (0PH104Z, 0PH134Z, 0PH144Z, 0PH204Z, 0PH234Z, and 0PH244Z) in MS–DRGs 166, 167, and 168 under MDC 4. Our findings are shown in the table below.

MS–DRGs FOR OTHER RESPIRATORY SYSTEM O.R. PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 166—All cases	22,938	10.2	$24,299
MS–DRG 166—Cases with principal diagnosis of rib fracture(s) and insertion of internal fixation device for the rib(s)	40	11.4	43,094
MS–DRG 167—All cases	10,815	5.7	13,252
MS–DRG 167—Cases with principal diagnosis of rib fracture(s) and insertion of internal fixation device for the rib(s)	10	6.7	30,617
MS–DRG 168—All cases	3,242	3.1	9,708
MS–DRG 168—Cases with principal diagnosis of rib fracture(s) and insertion of internal fixation device for the rib(s)	4	2	21,501

As shown in this table, there were a total of 22,938 cases in MS–DRG 166, with an average length of stay of 10.2 days and average costs of $24,299. In MS–DRG 166, we found 40 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), with an average length of stay of 11.4 days and average costs of $43,094. There were a total of 10,815 cases in MS–DRG 167, with an average length of stay of 5.7 days and average costs of $13,252. In MS–DRG 167, we found 10 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), with an average length of stay of 6.7 days and average costs of $30,617. There were a total of 3,242 cases in MS–DRG 168, with an average length of stay of 3.1 days and average costs of $9,708. In MS–DRG 168, we found 4 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), with an average length of stay of 2 days and average costs of $21,501. Overall, for MS–DRGs 166, 167, and 168, there were a total of 54 cases reporting a principal diagnosis of a rib fracture(s) with insertion of an internal fixation device for the rib(s), demonstrating that while rib fractures may require treatment, they are not typically corrected surgically. Our clinical advisors agree with the current assignment of procedure codes to MS–DRGs 166, 167, and 168 that may be reported to describe repair of a rib fracture under MDC 4, as well as the current assignment of procedure codes to MS–DRGs 515, 516, and 517 that may be reported to describe repair of a rib fracture under MDC 8. Our clinical advisors noted that initial, acute rib fractures can cause numerous respiratory related issues requiring various treatments and problems with the healing of a rib fracture are considered musculoskeletal issues.

We also note that the procedure codes submitted by the requestor may be reported for other indications and they are not restricted to reporting for repair of a rib fracture. Therefore, assignment of these codes to the MDC 4 MS–DRGs and the MDC 8 MS–DRGs is clinically appropriate.

To address the cases reporting procedure codes describing the repositioning of a rib(s) that are grouping to MS–DRGs 981, 982, and 983 when reported with a principal diagnosis of a rib fracture (initial encounter), we are proposing to add the following eight ICD–10–PCS procedure codes currently assigned to MDC 8 into MDC 4, in MS–DRGs 166, 167 and 168.

ICD–10–PCS code	Code description
0PS104Z	Reposition 1 to 2 ribs with internal fixation device, open approach.
0PS10ZZ	Reposition 1 to 2 ribs, open approach.
0PS134Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous approach.
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach.
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach.
0PS20ZZ	Reposition 3 or more ribs, open approach.
0PS234Z	Reposition 3 or more ribs with internal fixation device, percutaneous approach.
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach.

Our clinical advisors agree with this proposed addition to the classification structure because it is clinically appropriate and consistent with the other related ICD–10–PCS procedure codes that may be reported to describe rib fracture repair procedures with the insertion of an internal fixation device and are classified under MDC 4.

By adding the eight ICD–10–PCS procedure codes describing repositioning of the rib(s) that may be reported to describe a rib fracture repair procedure under the classification structure for MDC 4, these cases will no longer result in an MS–DRG assignment to the ''unrelated operating room procedures'' surgical class when reported with a diagnosis code under MDC 4.

We are inviting public comments on our proposals.

18. Proposed Changes to 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 National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention (CDC), 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 2019 at a public meeting held on September 12–13, 2017, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2017.

The Committee held its 2018 meeting on March 6–7, 2018. The deadline for submitting comments on these code proposals is scheduled for April 6, 2018. It was announced at this meeting that any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2018 would be included in the October 1, 2018 update to ICD–10–CM/ICD–10–PCS. As discussed in earlier sections of the preamble of the 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, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure 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. We are inviting public comments on the MDC and MS–DRG assignments for the new diagnosis and procedure codes as set forth in Table 6A—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, we are inviting public comments on the proposed severity level designations for the new diagnosis codes as set forth in Table 6A. and the proposed O.R. status for the new procedure codes as set forth in Table 6B. Because of the length of these tables, they are not published in the Addendum to this proposed rule. Rather, they are available via the Internet as discussed in section VI. of the Addendum to this proposed rule.

Live Webcast recordings of the discussions of procedure codes at the Committee's September 12–13, 2017 meeting and March 6–7, 2018 meeting can be obtained from the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/*

03_meetings.asp. The minutes of the discussions of diagnosis codes at the September 12–13, 2017 meeting and March 6–7, 2018 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 a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by E-mail to: *nchsicd10cm@cdc.gov.*

Questions and comments concerning the procedure codes should be submitted via E-mail 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) 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 2 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. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. 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 requester 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 summary report 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 approved for an expedited April l, 2018 implementation of a code at the September 12–13, 2017 Committee meeting. Therefore, there are not any new codes for implementation on April 1, 2018.

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/ICD–10–PCS 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

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR ICD–10–CM AND ICD–10–PCS CODES—Continued

Fiscal year	Number	Change
FY 2018:		
ICD–10–CM	71,704	+218
ICD–10–PCS	78,705	+2,916
Proposed FY 2019:		
ICD–10–CM	71,902	+198
ICD–10–PCS	78,533	−172

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.

At the September 12–13, 2017 and March 6–7, 2018 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that were to be implemented on October 1, 2018. We invited public comments on any code requests discussed at the September 12–13, 2017 and March 6–7, 2018 Committee meetings for implementation as part of the October 1, 2018 update. The deadline for commenting on code proposals discussed at the September 12–13, 2017 Committee meeting was November 13, 2017. The deadline for commenting on code proposals discussed at the March 6–7, 2018 Committee meeting was April 6, 2018.

19. Proposed 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 2019

In this FY 2019 IPPS/LTCH PPS proposed rule, for FY 2019, we are not proposing to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We are proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the table below.

We are soliciting public comments on our proposal to continue to include the existing MS–DRGs currently subject to the policy for replaced devices offered without cost or with credit and to not add any additional MS–DRGs to the policy.

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.
1	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.
1	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC.
1	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1	040	Peripheral, Cranial Nerve & Other Nervous System Procedures with MCC.
1	041	Peripheral, Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulator.
1	042	Peripheral, Cranial Nerve & Other Nervous System Procedures without CC/MCC.
3	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3	130	Major Head & Neck Procedures without CC/MCC.
5	215	Other Heart Assist System Implant.
5	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.
5	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.
5	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.
5	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.
5	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC.
5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	265	AICD Lead Procedures.
5	266	Endovascular Cardiac Valve Replacement with MCC.
5	267	Endovascular Cardiac Valve Replacement without MCC.
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.

MDC	MS–DRG	MS–DRG title
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
8	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement.
8	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.

20. Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues

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 cases where we are proposing to change the designation of procedure codes from non-O.R. 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. 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 newly designated as O.R. procedures. We are inviting public comments on these proposed MS–DRG assignments.

We also 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 below. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedures codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In addition, cases that contain O.R. procedures will map to MS–DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 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 the section below.

a. Percutaneous and Percutaneous Endoscopic Excision of Brain and Cerebral Ventricle

One requestor identified 22 ICD–10–PCS procedure codes that describe procedures involving transcranial brain and cerebral ventricle excision that the requestor stated would generally require the resources of an operating room. The 22 procedure codes are listed in the following table.

ICD–10–PCS procedure code	Code description
00B03ZX	Excision of brain, percutaneous approach, diagnostic.
00B13ZX	Excision of cerebral meninges, percutaneous approach, diagnostic.
00B23ZX	Excision of dura mater, percutaneous approach, diagnostic.
00B63ZX	Excision of cerebral ventricle, percutaneous approach, diagnostic.
00B73ZX	Excision of cerebral hemisphere, percutaneous approach, diagnostic.
00B83ZX	Excision of basal ganglia, percutaneous approach, diagnostic.
00B93ZX	Excision of thalamus, percutaneous approach, diagnostic.
00BA3ZX	Excision of hypothalamus, percutaneous approach, diagnostic.
00BB3ZX	Excision of pons, percutaneous approach, diagnostic.
00BC3ZX	Excision of cerebellum, percutaneous approach, diagnostic.
00BD3ZX	Excision of medulla oblongata, percutaneous approach, diagnostic.
00B04ZX	Excision of brain, percutaneous endoscopic approach, diagnostic.
00B14ZX	Excision of cerebral meninges, percutaneous endoscopic approach, diagnostic.
00B24ZX	Excision of dura mater, percutaneous endoscopic approach, diagnostic.
00B64ZX	Excision of cerebral ventricle, percutaneous endoscopic approach, diagnostic.
00B74ZX	Excision of cerebral hemisphere, percutaneous endoscopic approach, diagnostic.
00B84ZX	Excision of basal ganglia, percutaneous endoscopic approach, diagnostic.
00B94ZX	Excision of thalamus, percutaneous endoscopic approach, diagnostic.
00BA4ZX	Excision of hypothalamus, percutaneous endoscopic approach, diagnostic.
00BB4ZX	Excision of pons, percutaneous endoscopic approach, diagnostic.
00BC4ZX	Excision of cerebellum, percutaneous endoscopic approach, diagnostic.
00BD4ZX	Excision of medulla oblongata, percutaneous endoscopic approach, diagnostic.

The requestor stated that, although percutaneous burr hole biopsies are performed through smaller openings in the skull than open burr hole biopsies, these procedures require drilling or cutting through the skull using sterile technique with anesthesia for pain control. The requestor also noted that similar procedures involving percutaneous drainage of the subdural space are currently classified as O.R. procedures in Version 35 of the ICD–10

MS–DRGs. However, these 22 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that the 22 ICD–10–PCS codes be designated as O.R. procedures and assigned to MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively).

We agree with the requestor that these procedures typically require the resources of an operating room. Therefore, we are proposing to add these 22 ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 25, 26, and 27 in MDC 1 (Diseases and Disorders of the Nervous System). We are inviting public comments on our proposal.

b. Open Extirpation of Subcutaneous Tissue and Fascia

One requestor identified 22 ICD–10–PCS procedure codes that describe procedures involving open extirpation of subcutaneous tissue and fascia that the requestor stated would generally require the resources of an operating room. The 22 procedure codes are listed in the following table.

ICD–10–PCS procedure code	Code description
0JC00ZZ	Extirpation of matter from scalp subcutaneous tissue and fascia, open approach.
0JC10ZZ	Extirpation of matter from face subcutaneous tissue and fascia, open approach.
0JC40ZZ	Extirpation of matter from right neck subcutaneous tissue and fascia, open approach.
0JC50ZZ	Extirpation of matter from left neck subcutaneous tissue and fascia, open approach.
0JC60ZZ	Extirpation of matter from chest subcutaneous tissue and fascia, open approach.
0JC70ZZ	Extirpation of matter from back subcutaneous tissue and fascia, open approach.
0JC80ZZ	Extirpation of matter from abdomen subcutaneous tissue and fascia, open approach.
0JC90ZZ	Extirpation of matter from buttock subcutaneous tissue and fascia, open approach.
0JCB0ZZ	Extirpation of matter from perineum subcutaneous tissue and fascia, open approach.
0JCC0ZZ	Extirpation of matter from pelvic region subcutaneous tissue and fascia, open approach.
0JCD0ZZ	Extirpation of matter from right upper arm subcutaneous tissue and fascia, open approach.
0JCF0ZZ	Extirpation of matter from left upper arm subcutaneous tissue and fascia, open approach.
0JCG0ZZ	Extirpation of matter from right lower arm subcutaneous tissue and fascia, open approach.
0JCH0ZZ	Extirpation of matter from left lower arm subcutaneous tissue and fascia, open approach.
0JCJ0ZZ	Extirpation of matter from right hand subcutaneous tissue and fascia, open approach.
0JCK0ZZ	Extirpation of matter from left hand subcutaneous tissue and fascia, open approach.
0JCL0ZZ	Extirpation of matter from right upper leg subcutaneous tissue and fascia, open approach.
0JCM0ZZ	Extirpation of matter from left upper leg subcutaneous tissue and fascia, open approach.
0JCN0ZZ	Extirpation of matter from right lower leg subcutaneous tissue and fascia, open approach.
0JCP0ZZ	Extirpation of matter from left lower leg subcutaneous tissue and fascia, open approach.
0JCQ0ZZ	Extirpation of matter from right foot subcutaneous tissue and fascia, open approach.
0JCR0ZZ	Extirpation of matter from left foot subcutaneous tissue and fascia, open approach.

The requestor stated that these procedures involve making an open incision deeper than the skin under general anesthesia, and that irrigation and/or excision of devitalized tissue or cavity are often required and are considered inherent to the procedure. The requestor also stated that open drainage of subcutaneous tissue and fascia, open excisional debridement of subcutaneous tissue and fascia, and open nonexcisional debridement/extraction of subcutaneous tissue and fascia are designated as O.R. procedures, and that these 22 procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these 22 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that the 22 ICD–10–PCS procedure codes listed in the table be assigned to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, CC, and without CC/MCC, respectively).

We disagree with the requestor that these procedures typically require the resources of an operating room. Our clinical advisors indicated that these open extirpation procedures are minor procedures that can be performed outside of an operating room, such as in a radiology suite with CT or MRI guidance. We disagree that these procedures are similar to open drainage procedures. Therefore, we are proposing to maintain the status of these 22 ICD–10–PCS procedure codes as non-O.R. procedures. We are inviting public comments on our proposal.

c. Open Scrotum and Breast Procedures

One requestor identified 13 ICD–10–PCS procedure codes that describe procedures involving open drainage, open extirpation, and open debridement/excision of the scrotum and breast. The requestor stated that the 13 procedures listed in the following table involve making an open incision deeper than the skin under general anesthesia, and that irrigation and/or excision of devitalized tissue or cavity are often required and are considered inherent to the procedure. The requestor also stated that open drainage of subcutaneous tissue and fascia, open excisional debridement of subcutaneous tissue and fascia, open non-excisional debridement/extraction of subcutaneous tissue and fascia, and open excision of breast are designated as O.R. procedures, and that these 13 procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these 13 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment.

ICD–10–PCS procedure code	Code description
0V950ZZ	Drainage of scrotum, open approach.
0VB50ZZ	Excision of scrotum, open approach.
0VC50ZZ	Extirpation of matter from scrotum, open approach.

ICD–10–PCS procedure code	Code description
0H9U0ZZ	Drainage of left breast, open approach.
0H9T0ZZ	Drainage of right breast, open approach.
0H9V0ZZ	Drainage of bilateral breast, open approach.
0H9W0ZZ	Drainage of right nipple, open approach.
0H9X0ZZ	Drainage of left nipple, open approach.
0HCT0ZZ	Extirpation of matter from right breast, open approach.
0HCU0ZZ	Extirpation of matter from left breast, open approach.
0HCV0ZZ	Extirpation of matter from bilateral breast, open approach.
0HCW0ZZ	Extirpation of matter from right nipple, open approach.
0HCX0ZZ	Extirpation of matter from left nipple, open approach.

The requestor recommended that the 3 ICD–10–PCS scrotal procedure codes be assigned to MS–DRGs 717 and 718 (Other Male Reproductive System O.R. Procedures Except Malignancy with CC/MCC and without CC/MCC, respectively) and the 10 breast procedure codes be assigned to MS–DRGs 584 and 585 (Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC and without CC/MCC, respectively).

We agree with the requestor that these procedures typically require the resources of an operating room due to the nature of breast and scrotal tissue, as well as with the MS–DRG assignments recommended by the requestor. In addition, we believe that the scrotal codes should also be assigned to MS–DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with CC/MCC and without CC/MCC, respectively). Therefore, we are proposing to add these 13 ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 715, 716, 717, and 718 in MDC 12 (Diseases and Disorders of the Male Reproductive System) for the scrotal procedure codes and assigned to MS–DRGs 584 and 585 in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue & Breast) for the breast procedure codes. We are inviting public comments on our proposal.

d. Open Parotid Gland and Submaxillary Gland Procedures

One requestor identified eight ICD–10–PCS procedure codes that describe procedures involving open drainage and open extirpation of the parotid or submaxillary glands, shown in the following table.

ICD–10–PCS procedure code	Code description
0C980ZZ	Drainage of right parotid gland, open approach.
0C990ZZ	Drainage of left parotid gland, open approach.
0C9G0ZZ	Drainage of right submaxillary gland, open approach.
0C9H0ZZ	Drainage of left submaxillary gland, open approach.
0CC80ZZ	Extirpation of matter from right parotid gland, open approach.
0CC90ZZ	Extirpation of matter from left parotid gland, open approach.
0CCG0ZZ	Extirpation of matter from right submaxillary gland, open approach.
0CCH0ZZ	Extirpation of matter from left submaxillary gland, open approach.

The requestor stated that these procedures involve making an open incision through subcutaneous tissue, fascia, and potentially muscle, to reach and incise the parotid or submaxillary gland under general anesthesia, and that irrigation and/or excision of devitalized tissue or cavity may be required and are considered inherent to the procedure. The requestor also stated that open drainage of subcutaneous tissue and fascia, open excisional debridement of subcutaneous tissue and fascia, and open non-excisional debridement/extraction of subcutaneous tissue and fascia are designated as O.R. procedures, and that these eight procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these eight ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor requested that these procedures be assigned to MS–DRG 139 (Salivary Gland Procedures).

We agree with the requestor that these eight procedures typically require the resources of an operating room. Therefore, we are proposing to add these ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRG 139 in MDC 3 (Diseases and Disorders of the Ear, Nose, Mouth and Throat). We are inviting public comments on our proposal.

e. Removal and Reinsertion of Spacer; Knee Joint and Hip Joint

One requestor identified four sets of ICD–10–PCS procedure code combinations (eight ICD–10–PCS codes) that describe procedures involving open removal and insertion of spacers into the knee or hip joints, shown in the following table. The requestor stated that these are invasive procedures involving removal and reinsertion of devices into major joints and are performed in the operating room under general anesthesia. In the ICD–10 MS–DRGs Version 35, these four ICD–10–PCS procedure code combinations are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that CMS determine the most appropriate surgical DRGs for these procedures.

ICD–10–PCS procedure code	Code description
0SPC08Z	Removal of spacer from right knee joint, open approach.
0SHC08Z	Insertion of spacer into right knee joint, open approach.
0SPD08Z	Removal of spacer from left knee joint, open approach.
0SHD08Z	Insertion of spacer into left knee joint, open approach.
0SP908Z	Removal of spacer from right hip joint, open approach.
0SH908Z	Insertion of spacer into right hip joint, open approach.
0SPB08Z	Removal of spacer from left hip joint, open approach.
0SHB08Z	Insertion of spacer into left hip joint, open approach.

We agree with the requestor that these procedures typically require the resources of an operating room. However, our clinical advisors indicated that these codes should be designated as O.R. procedures even when reported as stand-alone procedures. Therefore, for the knee procedures, we are proposing to add these four ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 488 and 489 (Knee Procedures without Principal diagnosis of Infection with CC/MCC and without CC/MCC, respectively), both in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). For the hip procedures, we are proposing to add these four ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). We are inviting public comments on our proposal.

f. Endoscopic Dilation of Ureter(s) With Intraluminal Device

One requestor identified the following three ICD–10–PCS procedure codes that describe procedures involving endoscopic dilation of ureter(s) with intraluminal device.

ICD–10–PCS procedure code	Code description
0T778DZ	Dilation of left ureter with intraluminal device, via natural or artificial opening endoscopic.
0T768DZ	Dilation of right ureter with intraluminal device, via natural or artificial opening endoscopic.
0T788DZ	Dilation of bilateral ureters with intraluminal device, via natural or artificial opening endoscopic.

The requestor stated that these procedures involve the use of cystoureteroscopy to view the bladder and ureter and dilation under visualization, which are often followed by placement of a ureteral stent. The requestor also stated that endoscopic extirpation of matter from ureter, endoscopic biopsy of bladder, endoscopic dilation of bladder, endoscopic dilation of renal pelvis, and endoscopic dilation of the ureter without insertion of intraluminal device are all assigned to surgical DRGs, and that these three procedures should be designated as O.R. procedures for the same reason. In the ICD–10 MS–DRGs Version 35, these three ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor recommended that these procedures be assigned to MS–DRGs 656, 657, and 658 (Kidney and Ureter Procedures for Neoplasm with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 659, 660, and 661 (Kidney and Ureter Procedures for Non-Neoplasm with MCC, with CC, and without CC/MCC, respectively).

We agree with the requestor that these procedures typically require the resources of an operating room. In addition to the MS–DRGs recommended by the requestor, we believe that these procedure codes should also be assigned to other MS–DRGs, consistent with the assignment of other dilation of ureter procedures: MS–DRG 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively). Therefore, we are proposing to add the three ICD–10–PCS procedure codes identified by the requestor to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 656, 657, and 658 in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), MS–DRGs 659, 660, and 661 in MDC 11, MS–DRGs 907, 908, and 909 in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs), and MS–DRGs 957, 958, and 959 in MDC 24 (Multiple Significant Trauma). We are inviting public comments on our proposal.

g. Thoracoscopic Procedures of Pericardium and Pleura

One requestor identified seven ICD–10–PCS procedure codes that describe procedures involving thoracoscopic drainage of the pericardial cavity or pleural cavity, or extirpation of matter from the pleura, as shown in the following table.

ICD–10–PCS procedure code	Code description
0W9D4ZZ	Drainage of pericardial cavity, percutaneous endoscopic approach.
0W9D40Z	Drainage of pericardial cavity with drainage device, percutaneous endoscopic approach.
0W9D4ZX	Drainage of pericardial cavity, percutaneous endoscopic approach, diagnostic.

ICD–10–PCS procedure code	Code description
0W994ZX	Drainage of right pleural cavity, percutaneous endoscopic approach, diagnostic.
0W9B4ZX	Drainage of left pleural cavity, percutaneous endoscopic approach, diagnostic.
0BCP4ZZ	Extirpation of matter from left pleura, percutaneous endoscopic approach.
0BCN4ZZ	Extirpation of matter from right pleura, percutaneous endoscopic approach.

The requestor stated that these procedures involve making an incision through the chest wall and inserting a thoracoscope for visualization of thoracic structures during the procedure. The requestor also stated that some thoracoscopic procedures are assigned to surgical MS–DRGs, while other procedures are assigned to medical MS–DRGs. In the ICD–10 MS–DRGs Version 35, these seven ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment.

We agree with the requestor that these procedures typically require the resources of an operating room, as well as significant time and skill. During our review, we noted that the following two related procedures using the open approach also were not currently recognized as O.R. procedures:

ICD–10–PCS procedure code	Code description
0BCP0ZZ	Extirpation of matter from left pleura, open approach.
0BCN0ZZ	Extirpation of matter from right pleura, open approach.

Therefore, to be consistent with the MS–DRGs to which other approaches for procedures involving drainage or extirpation of matter from the pleura are assigned, we are proposing to add these nine ICD–10–PCS procedure codes to the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to one of the following MS–DRGs: MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 4 (Diseases and Disorders of the Respiratory System); MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 5 (Diseases and Disorders of the Circulatory System); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); 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; 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). We are inviting public comments on our proposal.

h. Open Insertion of Totally Implantable and Tunneled Vascular Access Devices

One requestor identified 20 ICD–10–PCS procedure codes that describe procedures involving open insertion of totally implantable and tunneled vascular access devices. The codes are identified in the following table.

ICD–10–PCS procedure code	Code description
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach.
0JH60XZ	Insertion of tunneled 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.
0JH80XZ	Insertion of tunneled 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.
0JHD0XZ	Insertion of tunneled 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.
0JHF0XZ	Insertion of tunneled 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.
0JHG0XZ	Insertion of tunneled 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.
0JHH0XZ	Insertion of tunneled 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.
0JHL0XZ	Insertion of tunneled 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.
0JHM0XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, open approach.
0JHN0WZ	Insertion of totally implantable vascular access device into right lower leg subcutaneous tissue and fascia, open approach.
0JHN0XZ	Insertion of tunneled vascular access device into right lower 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.
0JHP0XZ	Insertion of tunneled vascular access device into left lower leg subcutaneous tissue and fascia, open approach.

The requestor stated that open procedures to insert totally implantable vascular access devices (VAD) involve implantation of a port by open approach, cutting through subcutaneous tissue/fascia, placing the device, and

then closing tissues so that none of the device is exposed. The requestor explained that open procedures to insert tunneled VADs involve insertion of the catheter into central vasculature, and then open incision of subcutaneous tissue and fascia through which the device is tunneled. The requestor also indicated that these procedures require two ICD–10–PCS codes: One for the insertion of the VAD or port within the subcutaneous tissue; and one for percutaneous insertion of the central venous catheter that is connected to the device. The requestor further noted that, in MDC 11, cases with these procedure codes are assigned to surgical MS–DRGs and that insertion of infusion pumps by open approach groups to surgical MS–DRGs. The requestor recommended that these procedures be assigned to surgical MS–DRGs in MDC 09 as well. We examined the O.R. designations for this group of procedures and determined that they currently are designated as non-O.R. procedures for MDC 09 and MDC 11.

We agree with the requestor that procedures involving open insertion of totally implantable VAD procedures typically require the resources of an operating room. However, we disagree that the tunneled VAD procedures typically require the resources of an operating room. Therefore, we are proposing to update the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index to designate the 10 ICD–10–PCS procedure codes describing the totally implantable VAD procedures as O.R. procedures, which will continue to be assigned to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures, with CC, with MCC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). We note that these procedures already affect MS–DRG assignment to these MS–DRGs. However, if the procedure is unrelated to the principal diagnosis, it will be assigned to MS–DRGs 981, 982, and 983 instead of a medical MS-DRG. We are inviting public comments on our proposal.

i. Percutaneous Joint Reposition With Internal Fixation Device

One requestor identified 20 ICD–10–PCS procedure codes that describe procedures involving percutaneous joint reposition with internal fixation device, shown in the following table.

ICD–10–PCS procedure code	Code description
0SS034Z	Reposition lumbar vertebral joint with internal fixation device, percutaneous approach.
0SS334Z	Reposition lumbosacral joint with internal fixation device, percutaneous approach.
0SS534Z	Reposition sacrococcygeal joint with internal fixation device, percutaneous approach.
0SS634Z	Reposition coccygeal joint with internal fixation device, percutaneous approach.
0SS734Z	Reposition right sacroiliac joint with internal fixation device, percutaneous approach.
0SS834Z	Reposition left sacroiliac joint with internal fixation device, percutaneous approach.
0SS934Z	Reposition right hip joint with internal fixation device, percutaneous approach.
0SSB34Z	Reposition left hip joint with internal fixation device, percutaneous approach.
0SSC34Z	Reposition right knee joint with internal fixation device, percutaneous approach.
0SSD34Z	Reposition left knee joint with internal fixation device, percutaneous approach.
0SSF34Z	Reposition right ankle joint with internal fixation device, percutaneous approach.
0SSG34Z	Reposition left ankle joint with internal fixation device, percutaneous approach.
0SSH34Z	Reposition right tarsal joint with internal fixation device, percutaneous approach.
0SSJ34Z	Reposition left tarsal joint with internal fixation device, percutaneous approach.
0SSK34Z	Reposition right tarsometatarsal joint with internal fixation device, percutaneous approach.
0SSL34Z	Reposition left tarsometatarsal joint with internal fixation device, percutaneous approach.
0SSM34Z	Reposition right metatarsal-phalangeal joint with internal fixation device, percutaneous approach.
0SSN34Z	Reposition left metatarsal-phalangeal joint with internal fixation device, percutaneous approach.
0SSP34Z	Reposition right toe phalangeal joint with internal fixation device, percutaneous approach.
0SSQ34Z	Reposition left toe phalangeal joint with internal fixation device, percutaneous approach.

The requestor stated that reposition of the sacrum, femur, tibia, fibula, and other fractures of bone with internal fixation device by percutaneous approach are assigned to surgical DRGs, and that reposition of sacroiliac, hip, knee, and other joint locations with internal fixation should therefore also be assigned to surgical DRGs. In the ICD–10 MS–DRGs Version 35, these 20 ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment.

We disagree with the requestor that these procedures typically require the resources of an operating room, as these procedures are not as invasive as the bone reposition procedures referenced by the requestor. Our clinical advisors advised that these procedures are typically performed in a radiology suite. Therefore, we are proposing to maintain the status of these 20 ICD–10–PCS procedure codes as non-O.R. procedures. We are inviting public comments on our proposal.

j. Endoscopic Destruction of Intestine

One requestor identified four ICD–10–PCS procedure codes that describe procedures involving endoscopic destruction of the intestine, as shown in the following table.

ICD–10–PCS procedure code	Code description
0D5A8ZZ	Destruction of jejunum, via natural or artificial opening endoscopic.
0D5B8ZZ	Destruction of ileum, via natural or artificial opening endoscopic.
0D5C8ZZ	Destruction of ileocecal valve, via natural or artificial opening endoscopic.
0D588ZZ	Destruction of small intestine, via natural or artificial opening endoscopic.

The requestor stated that these procedures are rarely performed in the operating room. In the ICD–10 MS–DRGs Version 35, these 20 ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment.

We agree with the requestor that these procedures do not typically require the resources of an operating room. Therefore, we are proposing to remove these four procedure codes from the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. We are inviting public comments on our proposal.

k. Drainage of Lower Lung Via Natural or Artificial Opening Endoscopic, Diagnostic

One requestor identified the following ICD–10–PCS procedure codes that describe procedures involving endoscopic drainage of the lung via natural or artificial opening for diagnostic purposes.

ICD–10–PCS procedure code	Code description
0B9J8ZX	Drainage of left lower lung lobe, via natural or artificial opening endoscopic, diagnostic.
0B9F8ZX	Drainage of right lower lung lobe, via natural or artificial opening endoscopic, diagnostic.

The requestor stated that these procedures are rarely performed in the operating room.

We agree with the requestor that these procedures do not require the resources of an operating room. In addition, while we were reviewing this comment, we identified three additional related codes:

ICD–10–PCS procedure code	Code description
0B9D8ZX	Drainage of right middle lung lobe, via natural or artificial opening endoscopic, diagnostic.
0B9C8ZX	Drainage of right upper lung lobe, via natural or artificial opening endoscopic, diagnostic.
0B9G8ZX	Drainage of left upper lung lobe, via natural or artificial opening endoscopic, diagnostic.

In the ICD–10 MS–DRGs Version 35, these ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment.

We are proposing to remove ICD–10–PCS procedure codes 0B9J8ZX, 0B9F8ZX, 0B9D8ZX, 0B9C8ZX, and 0B9G8ZX from the FY 2019 ICD–10 MS–DRGs Version 36 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. We are inviting public comments on our proposal.

G. Recalibration of the Proposed FY 2019 MS–DRG Relative Weights

1. Data Sources for Developing the Proposed Relative Weights

In developing the proposed FY 2019 system of weights, we are proposing to use two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2017 MedPAR data used in this proposed rule include discharges occurring on October 1, 2016, through September 30, 2017, based on bills received by CMS through December 31, 2017, 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 2017 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,652,400 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, 2017 update of the FY 2017 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 2019 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 2019 relative weights are based on the ICD-10-CM diagnoses and ICD–10–PCS procedure codes from the FY 2017 MedPAR claims data, grouped through the ICD-10 version of the proposed FY 2019 GROUPER (Version 36).

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, 2017 update of the FY 2016 HCRIS for calculating the proposed FY 2019 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.2. of the preamble of this proposed rule, we calculated the proposed FY 2019 relative weights based on 19 CCRs, as we did for FY 2018. The methodology we are proposing to use to calculate the FY 2019 MS–DRG cost-based relative weights based on claims data in the FY 2017 MedPAR file and data from the FY 2016 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2019 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 2017 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 92.5 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 they 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.

The participation of hospitals in the BPCI initiative is set to conclude on September 30, 2018. The participation of hospitals in the Bundled Payments for Care Improvement (BPCI) Advanced model is set to start 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 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 webpage on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*. For FY 2019, consistent with how we have treated hospitals that participated in the BPCI Initiative, 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, as noted above, these hospitals are still receiving IPPS payments under section 1886(d) of the Act.

The charges for each of the proposed 19 cost groups for each claim were standardized to remove the effects of differences in proposed area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable proposed 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 proposed 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 proposed 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 2016 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table 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 stakeholders have comments about the groupings in this table, 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 2019 relative weights and the changes in relative weights from FY 2018.

BILLING CODE 4120–01–P

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X					
	Ward Charges	015X					
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Burn Intensive Care Unit	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
				Other Special Care Unit	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_64	
				Drugs Charged To Patient	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_73	
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_71	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_96	
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_97	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_97	
Implantable Devices		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_72	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_66	
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_68	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_65	
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
						C_1_C7_50	
		071X		Recovery Room	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_51	
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
						C_1_C7_52	
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_53	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69
						C_1_C7_69	
Cardiac Catheteri-zation		0481		Cardiac Catheterization	C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
						C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60
						C_1_C7_60	
				PBP Clinic Laboratory	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Services			
						C_1_C7_61	
		074X, 086X		Electro-Encephalography	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70
						C_1_C7_70	
Radiology	Radiology Charges	032X, 040X		Radiology – Diagnostic	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_54	
		028x, 0331, 0332, 0333,		Radiology – Therapeutic	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
		0335, 0339, 0342					
		0343 and 344		Radioisotope	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_56	
Computed Tomography (CT) Scan	CT Scan Charges	035X		Computed Tomography (CT) Scan	C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
						C_1_C7_57	
Magnetic Resonance Imaging (MRI)	MRI Charges	061X		Magnetic Resonance Imaging (MRI)	C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
						C_1_C7_58	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_62	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_63	
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X, 053X					
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X					
	Renal Dialysis	0800X		Renal Dialysis	C_1_C5_74	C_1_C6_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges	080X and 082X-088X				C_1_C7_74	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Home Program Dialysis	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94
						C_1_C7_94	
	Outpatient Service Charges	049X		ASC (Non Distinct Part)	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
	Lithotripsy Charge	079X				C_1_C7_75	
				Other Ancillary	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
						C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90
						C_1_C7_90	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Observation beds	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_92.01	
	Professional Fees Charges	096X, 097X, and 098X		Other Outpatient Services	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_93	
	Ambulance Charges	054X		Ambulance	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_95	
				Rural Health Clinic	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
						C_1_C7_88	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				FQHC	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_89	

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3. Development of Proposed National Average CCRs

We developed the proposed national average CCRs as follows:

Using the FY 2016 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. We then created CCRs for each provider for each cost center (see prior table 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. We then 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 proposed 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each proposed MS–DRG to produce a total standardized cost for the proposed MS–DRG. The average standardized cost for each proposed MS–DRG was then computed as the total standardized cost for the proposed MS–DRG divided by the transfer-adjusted case count for the proposed MS–DRG. We calculated the transfer-adjusted discharges for use in the calculation of the Version 36 MS–DRG relative weights using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program discussed in section IV.A.2.b. of the preamble of this proposed rule. For the purposes of calculating the normalization factor, we used the transfer-adjusted discharges with the expanded postacute care transfer policy for Version 35 as well. (When we calculate the normalization factor, we calculate the transfer-adjusted case count for the prior GROUPER version (in this case Version 35) and multiply by the weights of that GROUPER. We then compare that pool to the transfer-adjusted case count using the new GROUPER version.) The average cost for each proposed MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight.

The proposed FY 2019 cost-based relative weights were then normalized by a proposed adjustment factor of 1.760698 so that the average case weight after recalibration was equal to the average case weight before recalibration. The proposed 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 2019 are as follows:

Group	CCR
Routine Days	0.451
Intensive Days	0.373
Drugs	0.196
Supplies & Equipment	0.299
Implantable Devices	0.321
Therapy Services	0.312
Laboratory	0.116
Operating Room	0.185
Cardiology	0.107
Cardiac Catheterization	0.115
Radiology	0.149
MRIs	0.076
CT Scans	0.037
Emergency Room	0.165
Blood and Blood Products	0.306
Other Services	0.355
Labor & Delivery	0.363
Inhalation Therapy	0.163
Anesthesia	0.081

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 2019. Using data from the FY 2017 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2019, 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 proposed low-volume MS–DRGs by adjusting their final FY 2018 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown:

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2018 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 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2018 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 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	Final FY 2018 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

We are inviting public comments on our proposals.

H. Proposed Add-On Payments for New Services and Technologies for FY 2019

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 specify 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. Below 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).

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 technology 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 a technology 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).

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. Table 10 that was released with the FY 2018 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service or technology add-on payments for FY 2019. We refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Tables.html* to download and view Table 10.

As previously stated, Table 10 that is released with each proposed and final rule contains the thresholds that we use to evaluate applications for new medical service and technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. For example, the thresholds in Table 10 released with the FY 2018 IPPS/LTCH PPS final rule are applicable to FY 2019 new technology applications. Beginning with the thresholds for FY 2020 and future years, we are proposing to provide the thresholds that we previously included in Table 10 as one of our data files posted via the Internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html,* which is the same URL where the impact data files associated with the rulemaking for the applicable fiscal year are posted. We believe that this proposed change in the presentation of this information, specifically in the data files rather than in a Table 10, will clarify for the public that the listed thresholds will be used for new technology add-on payment applications for the next fiscal year (in this case, for FY 2020) rather than for the fiscal year that is otherwise the subject of the rulemaking (in this case, for FY 2019), while continuing to furnish the same information on the new technology add-on payment thresholds for applications for the next fiscal year as has been provided in previous fiscal years. Accordingly, we would no longer include Table 10 as one of our IPPS tables, but would instead include the thresholds applicable to the next fiscal year (beginning with FY 2020) in the data files associated with the prior fiscal year (in this case, FY 2019).

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed 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.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We

refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902).)

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. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (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) 50 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or medical service.

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 later years have not been subjected to budget neutrality.

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 for their new medical service or technology by July 1 of the year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) 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.*

We note that applicants for add-on payments for new medical services or technologies for FY 2020 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, 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 2020, 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; it is currently approved under OMB control number 0938–1347, which expires on December 31, 2020.

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 2019 prior to publication of this FY 2019 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on December 4, 2017 (82 FR 57275), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 13, 2018. 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 each of the FY 2019 new medical service and technology add-on payment applications before the publication of this FY 2019 IPPS/LTCH PPS proposed rule.

Approximately 150 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 town hall on the CMS YouTube web page at: *https://www.youtube.com/watch?v=9niqfxXe4oA&t=217s.* 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 February 23, 2018, in our evaluation of the new technology add-on payment applications for FY 2019 in this FY 2019 IPPS/LTCH PPS proposed rule.

In response to the published notice and the February 13, 2018 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2019 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 (82 FR 57275 through 57277), 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 2019. Therefore, we are not summarizing those written comments in this proposed rule. In section II.H.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, at the end of each discussion of the individual applications.

Comment: One commenter recommended that the specific criteria that CMS uses in making substantial clinical improvement determinations be codified in the regulations to more explicitly clarify that the new medical service or technology will meet the substantial clinical improvement criterion if it: (a) Results in a reduction of the length of a hospital stay; (b) improves patient quality of life; (c) creates long-term clinical efficiencies in treatment; (d) addresses patient-centered objectives as defined by the Secretary; or (e) meets such other criteria as the Secretary may specify. The commenter stated that criteria similar to these were defined in the September 2001 New Technology Final Rule (66 FR 46913 through 46914). The commenter also recommended that final decisions on new technology add-on payment applications should explicitly discuss how a technology or treatment meets or fails to meet these specific criteria.

Response: We appreciate the commenter's recommendation. However, in the September 2001 New Technology Final Rule (66 FR 46913 through 46914), we explained how we evaluate if a new medical service or technology would meet the substantial clinical improvement criterion. Specifically, we stated that we evaluate a request for new technology payments against the following criteria to determine if the new medical service or technology would represent a substantial clinical improvement over existing technologies:

• The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

• The device 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. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

• Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments.

We typically require the applicant to submit evidence that the technology meets one or more of these standards. Regarding whether the use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments, we provided examples of improved clinical outcomes.

In response to the commenter's recommendation that final decisions on new technology add-on applications explicitly discuss how a technology or treatment meets or fails to meet these specific standards, we believe that we provide this explanation when approving or denying an application for new technology add-on payments in the final rule.

Comment: One commenter stated that the United States Food and Drug Administration Modernization Act (FDAMA) of 1997 established a category of medical devices and diagnostics that are eligible for priority FDA review. The commenter explained that, to qualify, products must be designated by the FDA as offering the potential for significant improvements in the diagnosis or treatment of the most serious illnesses, including those that are life-threatening or irreversibly debilitating. The commenter indicated that the processes by which products meeting the statutory standard for priority treatment are considered by the FDA are spelled out in greater detail in FDA's Expedited Access Program (EAP), and in the 21st Century Cures Act. The commenter believed that the criteria for priority FDA review are very similar to the substantial clinical improvement criteria and, therefore, devices used in the inpatient setting determined to be eligible for expedited review and approved by the FDA should automatically be considered as meeting the substantial clinical improvement criterion, without further consideration by CMS.

Another commenter stated that CMS historically has noted that a new technology is an appropriate candidate for an additional payment ''when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.'' The commenter believed that this standard was created for medical devices because they dominated new technology of the time. The commenter recommended that this standard not be applied to regenerative medicine therapies because it believed these criteria are likely outside Congressional intent and inconsistent with some of the congressionally-created FDA approval rules related to expedited approval programs. The commenter explained that the FDA defines congressionally-created ''breakthrough therapy'' and designates a therapy as such if it ''may demonstrate substantial improvement over existing therapies.'' In addition, the commenter stated that the Regenerative Medicine Advanced Therapy (RMAT) designation is granted to products that are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and if clinical evidence shows that it has the potential to meet an unmet medical need.

Response: The FDA provides a number of different types of approvals and designations for devices, drugs, and other medical products. As required by section 1886(d)(5)(K)(viii) of the Act, CMS provides a mechanism for public input, before the publication of the proposed rule, regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under Medicare Part A. We believe that the criteria explained in the September 2001 New Technology Final Rule (66 FR 46914) are consistent with the statutory requirements for evaluating new medical services and technologies and continue to be relevant to determining whether a new medical service or technology represents a substantial clinical improvement over existing technologies. If the technology has a status designated by the FDA that is similar to the standards and conditions required to demonstrate substantial clinical improvement under the new technology add-on payment criterion, or is designated as a breakthrough therapy, the technology should be able to demonstrate with evidence that it meets the new technology add-on payment substantial clinical improvement criterion. Finally, we do take FDA approvals into consideration in our evaluation and determination of approvals and denials of new technology add-on payment applications.

Comment: One commenter stated that, for technologies without a special FDA designation, the substantial clinical improvement standard is an inappropriate clinical standard for the family of regenerative therapies because it creates a threshold that is too high and unrealistic to meet. The commenter believed that requiring a vague standard such as ''substantial clinical improvement'' ignores that innovation is achieved incrementally. The commenter asserted that by only approving new technologies that can achieve this standard for new technology add-on payments, CMS' policy is at cross-purposes with promoting innovation because many worthy technologies will not be approved by CMS, which denies the general population the opportunity of having the chance to learn and otherwise benefit from those technologies.

The commenter also stated that CMS has questioned how substantial clinical improvement can be measured and achieved via small clinical trials with FDA approval. The commenter stated that it is concerned that this view sets a dangerous precedent by significantly undervaluing new transformative therapies. The commenter added that the FDA often only requires single-arm trials with small numbers of patients for these products because it is often not feasible for product developers to provide data on a large number of patients, especially those working in rare diseases as many regenerative and advanced therapeutic developers are. The commenter stated that, given the transformative nature of the products, this should not be a reason for CMS to deny a new medical service or technology add-on payment.

Response: We believe that the September 2001 New Technology Final Rule (66 FR 46914) clearly defines the criteria that CMS uses to evaluate and determine if a new medical service or technology represents a substantial clinical improvement. In addition, we accept different types of data (for example, peer-reviewed articles, study results, or letters from major associations, among others) that demonstrate and support the substantial clinical improvement associated with the new medical service or technology's use. In addition to clinical data, we will consider any evidence that would support the conclusion of a substantial clinical improvement associated with a new medical service or technology. Therefore, we believe that we consider an appropriate range of evidence.

Comment: One commenter stated that CMS should consider FDA approval and the associated evidence base leading to such an approval as a standard for meeting the substantial clinical improvement criterion. The commenter believed that additional factors such as improvements in patient quality of life, creation of long-term clinical efficiencies in care, reductions in the use of other healthcare services, or other such criteria should be incorporated into the CMS determination process for whether a new medical service or technology demonstrates or represents a substantial clinical improvement over existing technologies. The commenter believed that, by including these additional factors, CMS would align payment rates such that patients would have access to the highest standard of treatment for all transformative therapies representing a substantial clinical improvement for the patient populations they serve, and it would be recognized as such by the receipt of new technology add-on payments.

Response: As stated earlier, one of the standards we use to determine whether a new medical service or technology represents a substantial clinical improvement over existing technologies is to evaluate whether the use of the device, drug, service, or technology significantly improves clinical outcomes for a patient population as compared to currently available treatments, and we provided examples of improved clinical outcomes in the September 2001 New Technology Final Rule (66 FR 46913 through 46914).

Comment: One commenter encouraged CMS to ensure appropriate implementation of the substantial clinical improvement criterion under the applicable Medicare statutory provisions and regulations, as applied to radiopharmaceuticals and other nuclear medicine technologies that can lead to significant benefits and advances in the diagnosis and treatment of many diseases. The commenter recommended that CMS apply an appropriately flexible standard for purposes of assessing whether a technology represents a substantial clinical improvement over other existing, available therapies. The commenter asserted that a flexible standard for this purpose must include new products and new formulations of products that increase the safety or efficacy, or both, relative to current treatments. The commenter believed that failing to recognize a technology that enhances the safety and/or efficacy of existing options as both ''new'' and a

''substantial clinical improvement'' over existing options would be a disservice to Medicare beneficiaries and to the mission of the Medicare program.

The commenter encouraged CMS to give consideration to the importance of technologies that make radiotherapies safer, as well as those that lead to increased efficacy. The commenter explained that minimizing a patient's exposure to radiation, while also maximizing the effectiveness of the radiotherapy dose results in highly significant clinical improvements for patients, including in specific areas that CMS has expressly identified as relevant to the substantial clinical improvement criterion.

Response: As stated earlier, we believe that the criteria explained in the September 2001 New Technology Final Rule (66 FR 46914) are consistent with the statutory requirements for evaluating new medical services and technologies and continue to be relevant to determining whether a new medical service or technology represents a substantial clinical improvement over existing technologies.

We believe that it is important to maintain an open dialogue regarding the IPPS new technology add-on payment process, and we appreciate all of the commenters' input and recommendations.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH 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 2019 Status of Technologies Approved for FY 2018 Add-On Payments

a. Defitelio® (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for defibrotide (Defitelio®), a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multiorgan dysfunction. VOD, also known as sinusoidal obstruction syndrome (SOS), is a potentially life-threatening complication of hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients treated with HSCT who develop VOD with multi-organ failure face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used. The applicant asserted that Defitelio® improves the survival rate of patients diagnosed with VOD with multi-organ failure by 23 percent.

Defitelio® received Orphan Drug Designation for the treatment of VOD in 2003 and for the prevention of VOD in 2007. It has been available to patients as an investigational drug through an expanded access program since 2006. The applicant's New Drug Application (NDA) for Defitelio® received FDA approval on March 30, 2016. The applicant confirmed that Defitelio® was not available on the U.S. market as of the FDA NDA approval date of March 30, 2016. According to the applicant, commercial packaging could not be completed until the label for Defitelio® was finalized with FDA approval, and that commercial shipments of Defitelio® to hospitals and treatment centers began on April 4, 2016. Therefore, we agreed that, based on this information, the newness period for Defitelio® begins on April 4, 2016, the date of its first commercial availability.

The applicant received approval to use unique ICD–10–PCS procedure codes to describe the use of Defitelio®, with an effective date of October 1, 2016. The approved ICD–10PCS procedure codes are: XW03392 (Introduction of defibrotide sodium anticoagulant into peripheral vein, percutaneous approach); and XW04392 (Introduction of defibrotide sodium anticoagulant into central vein, percutaneous approach).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Defitelio® and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Defitelio® for new technology add-on payments for FY 2017 (81 FR 56906). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 25 mg/kg/day for a minimum of 21 days of treatment. The recommended dose is 6.25 mg/kg given as a 2-hour intravenous infusion every 6 hours. Dosing should be based on a patient's baseline body weight, which is assumed to be 70 kg for an average adult patient. All vials contain 200 mg at a cost of $825 per vial. Therefore, we determined that cases involving the use of the Defitelio® technology would incur an average cost per case of $151,800 (70 kg adult × 25 mg/kg/day × 21 days = 36,750 mg per patient/200 mg vial = 184 vials per patient × $825 per vial = $151,800). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Defitelio® is $75,900.

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 Defitelio®, we considered the beginning of the newness period to commence on the first day Defitelio® was commercially available (April 4, 2016). Because the 3-year anniversary date of the entry of the Defitelio® onto the U.S. market (April 4, 2019) will occur in the latter half of FY 2019, we are proposing to continue new technology add-on payments for this technology for FY 2019. We are

proposing that the maximum payment for a case involving Defitelio® would remain at $75,900 for FY 2019. We are inviting public comments on our proposal to continue new technology add-on payments for Defitelio® for FY 2019.

b. EDWARDS INTUITY Elite™ Valve System (INTUITY) and LivaNova Perceval Valve (Perceval)

Two manufacturers, Edwards Lifesciences and LivaNova, submitted applications for new technology add-on payments for FY 2018 for the INTUITY Elite™ Valve System (INTUITY) and the Perceval Valve (Perceval), respectively. Both of these technologies are prosthetic aortic valves inserted using surgical aortic valve replacement (AVR). Aortic valvular disease is relatively common, primarily manifested by aortic stenosis. Most aortic stenosis is due to calcification of the valve, either on a normal tri-leaflet valve or on a congenitally bicuspid valve. The resistance to outflow of blood is progressive over time, and as the size of the aortic orifice narrows, the heart must generate increasingly elevated pressures to maintain blood flow. Symptoms such as angina, heart failure, and syncope eventually develop, and portend a very serious prognosis. There is no effective medical therapy for aortic stenosis, so the diseased valve must be replaced or, less commonly, repaired.

According to both applicants, the INTUITY valve and the Perceval valve are the first sutureless, rapid deployment aortic valves that can be used for the treatment of patients who are candidates for surgical AVR. Because potential cases representing patients who are eligible for treatment using the INTUITY and the Perceval aortic valve devices would group to the same MS–DRGs, and we believe that these devices 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 determined these two devices are substantially similar to each other and that it was appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS.

With respect to the newness criterion, the INTUITY valve received FDA approval on August 12, 2016, and was commercially available on the U.S. market on August 19, 2016. The Perceval valve received FDA approval on January 8, 2016, and was commercially available on the U.S. market on February 29, 2016. In accordance with our policy, we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38120) that we believe it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, we stated that the beginning of the newness period is February 29, 2016, when the Perceval valve became commercially available. The ICD–10–PCS code approved to identify procedures involving the use of both devices when surgically implanted is ICD–10–PCS code X2RF032 (Replacement of aortic valve using zooplastic tissue, rapid deployment technique, open approach, new technology group 2).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the INTUITY and Perceval valves and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved the INTUITY and Perceval valves for new technology add-on payments for FY 2018 (82 FR 38125). We stated that we believed that the use of a weighted-average of the cost of the standard valves based on the projected number of cases involving each technology to determine the maximum new technology add-on payment was most appropriate. To compute the weighted-cost average, we summed the total number of projected cases for each of the applicants, which equaled 2,429 cases (1,750 plus 679). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 72 percent for the INTUITY and 28 percent for the Perceval valve. We then multiplied the cost per case for the manufacturer specific valve by the case-weighted percentage (0.72 * $12,500 = $9,005.76 for INTUITY and 0.28 * $11,500 = $3,214.70 for the Perceval valve). This resulted in a case-weighted average cost of $12,220.46 for the valves. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the INTUITY or Perceval valves is $6,110.23 for FY 2018.

With regard to the newness criterion for the INTUITY and Perceval valves, we considered the newness period for the INTUITY and Perceval valves to begin February 29, 2016. 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 technology onto the U.S. market (February 29, 2019) will occur in the first half of FY 2019, we are proposing to discontinue new technology add-on payments for the INTUITY and Perceval valves for FY 2019. We are inviting public comments on our proposal to discontinue new technology add-on payments for the INTUITY and Perceval valves.

c. GORE® EXCLUDER® Iliac Branch Endoprosthesis (Gore IBE Device)

W. L. Gore and Associates, Inc. submitted an application for new technology add-on payments for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device) for FY 2017. The device consists of two components: The Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The applicant indicated that each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. According to the applicant, the device is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.

With regard to the newness criterion, the applicant received pre-market FDA approval of the GORE IBE device on February 29, 2016. The following procedure codes describe the use of this technology: 04VC0EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VC3EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VC4EZ (Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VD0EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, open approach); 04VD3EZ (Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach); 04VD4EZ (Restriction of left common iliac artery with branched or fenestrated

intraluminal device, one or two arteries, percutaneous endoscopic approach).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the GORE IBE device and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved the GORE IBE device for new technology add-on payments for FY 2017 (81 FR 56909). With the new technology add-on payment application, the applicant indicated that the total operating cost of the GORE IBE device is $10,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the GORE IBE device is $5,250.

With regard to the newness criterion for the GORE IBE device, we considered the beginning of the newness period to commence when the GORE IBE device received FDA approval on February 29, 2016. 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 GORE IBE device onto the U.S. market (February 28, 2019) will occur in the first half of FY 2019, we are proposing to discontinue new technology add-on payments for this technology for FY 2019. We are inviting public comments on our proposal to discontinue new technology add-on payments for the GORE IBE device.

d. Idarucizumab

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2017 for Idarucizumab, a product developed as an antidote to reverse the effects of PRADAXAR (Dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc.

Dabigatran is an oral direct thrombin inhibitor currently indicated: (1) To reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; (3) to reduce the risk of recurrence of DVT and PE in patients who have been previously treated; and (4) for the prophylaxis of DVT and PE in patients who have undergone hip replacement surgery. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode. Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations.

Idarucizumab was approved by the FDA on October 16, 2015. Idarucizumab is indicated for the use in the treatment of patients who have been administered Pradaxa when reversal of the anticoagulant effects of dabigatran is needed for emergency surgery or urgent medical procedures or in life-threatening or uncontrolled bleeding.

The applicant was granted approval to use unique ICD–10–PCS procedure codes that became effective October 1, 2016, to describe the use of this technology. The approved ICD–10–PCS procedure codes are: XW03331 (Introduction of Idarucizumab, Dabigatran reversal agent into peripheral vein, percutaneous approach, new technology group 1); and XW04331 (Introduction of Idarucizumab, Dabigatran reversal agent into central vein, percutaneous approach, new technology group 1).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Idarucizumab and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Idarucizumab for new technology add-on payments for FY 2017 (81 FR 56897). With the new technology add-on payment application, the applicant indicated that the total operating cost of Idarucizumab is $3,500. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving Idarucizumab is $1,750.

With regard to the newness criterion for Idarucizumab, we considered the beginning of the newness period to commence when Idarucizumab was approved by the FDA on October 16, 2015. 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 Idarucizumab onto the U.S. market will occur in the first half of FY 2019 (October 15, 2018), we are proposing to discontinue new technology add-on payments for this technology for FY 2019. We are inviting public comments on our proposal to discontinue new technology add-on payments for Idarucizumab.

e. Ustekinumab (Stelara®)

Janssen Biotech submitted an application for new technology add-on payments for the Stelara® induction therapy for FY 2018. Stelara® received FDA approval as an intravenous (IV) infusion treatment of Crohn's disease (CD) on September 23, 2016, which added a new indication for the use of Stelara® and route of administration for this monoclonal antibody. IV infusion of Stelara® is indicated for the treatment of adult patients (18 years and older) diagnosed with moderately to severely active CD who have: (1) Failed or were intolerant to treatment using immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker; or (2) failed or were intolerant to treatment using one or more TNF blockers. Stelara® for IV infusion has only one purpose, induction therapy. Stelara® must be administered intravenously by a health care professional in either an inpatient hospital setting or an outpatient hospital setting.

Stelara® for IV infusion is packaged in single 130 mg vials. Induction therapy consists of a single IV infusion dose using the following weight-based dosing regimen: Patients weighing less than (<)55 kg are administered 260 mg of Stelara® (2 vials); patients weighing more than (>)55 kg, but less than (<)85 kg are administered 390 mg of Stelara® (3 vials); and patients weighing more than (>)85 kg are administered 520 mg of Stelara® (4 vials). An average dose of Stelara® administered through IV infusion is 390 mg (3 vials). Maintenance doses of Stelara® are administered at 90 mg, subcutaneously, at 8-week intervals and may occur in the outpatient hospital setting.

CD is an inflammatory bowel disease of unknown etiology, characterized by transmural inflammation of the gastrointestinal (GI) tract. Symptoms of CD may include fatigue, prolonged diarrhea with or without bleeding, abdominal pain, weight loss and fever. CD can affect any part of the GI tract

including the mouth, esophagus, stomach, small intestine, and large intestine. Conventional pharmacologic treatments of CD include antibiotics, mesalamines, corticosteroids, immunomodulators, tumor necrosis alpha (TNFα) inhibitors, and anti-integrin agents. Surgery may be necessary for some patients diagnosed with CD in which conventional therapies have failed.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Stelara® and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved Stelara® for new technology add-on payments for FY 2018 (82 FR 38129). Cases involving Stelara® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW033F3 (Introduction of other New Technology therapeutic substance into peripheral vein, percutaneous approach, new technology group 3). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 390 mg (3 vials) at a hospital acquisition cost of $1,600 per vial (for a total of $4,800). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of Stelara® is $2,400.

With regard to the newness criterion for Stelara®, we considered the beginning of the newness period to commence when Stelara® received FDA approval as an IV infusion treatment of Crohn's disease (CD) on September 23, 2016. Because the 3-year anniversary date of the entry of Stelara® onto the U.S. market (September 23, 2019) will occur after FY 2019, we are proposing to continue new technology add-on payments for this technology for FY 2019. We are proposing that the maximum payment for a case involving Stelara® would remain at $2,400 for FY 2019. We are inviting public comments on our proposal to continue new technology add-on payments for Stelara® for FY 2019.

f. Vistogard™ (Uridine Triacetate)

BTG International Inc. submitted an application for new technology add-on payments for the Vistogard™ for FY 2017. Vistogard™ was developed as an emergency treatment for Fluorouracil toxicity.

Chemotherapeutic agent 5-fluorouracil (5–FU) is used to treat specific solid tumors. It acts upon deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the body, as uracil is a naturally occurring building block for genetic material. Fluorouracil is a fluorinated pyrimidine. As a chemotherapy agent, Fluorouracil is absorbed by cells and causes the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. According to the applicant, the byproducts fluorodoxyuridine monophosphate (F–dUMP) and floxuridine triphosphate (FUTP) are believed to do the following: (1) Reduce DNA synthesis; (2) lead to DNA fragmentation; and (3) disrupt RNA synthesis. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. With different tumor treatments, different dosages, and different dosing schedules, there is a risk for toxicity in these patients. Patients may suffer from fluorouracil toxicity/death if 5–FU is delivered in slight excess or at faster infusion rates than prescribed. The cause of overdose can happen for a variety of reasons including: Pump malfunction, incorrect pump programming or miscalculated doses, and accidental or intentional ingestion.

Vistogard™ is an antidote to Fluorouracil toxicity and is a prodrug of uridine. Once the drug is metabolized into uridine, it competes with the toxic byproduct FUTP in binding to RNA, thereby reducing the impact FUTP has on cell death.

With regard to the newness criterion, Vistogard™ received FDA approval on December 11, 2015. However, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56910), due to the delay in Vistogard™'s commercial availability, we considered the newness period to begin March 2, 2016, instead of December 11, 2015. The applicant noted that the Vistogard™ is the first FDA-approved antidote used to reverse fluorouracil toxicity. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure code: XW0DX82 (Introduction of Uridine Triacetate into Mouth and Pharynx, External Approach, new technology group 2). The new code became effective on October 1, 2016.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for Vistogard™ and consideration of the public comments we received in response to the FY 2017 IPPS/LTCH PPS proposed rule, we approved Vistogard™ for new technology add-on payments for FY 2017 (81 FR 56912). With the new technology add-on payment application, the applicant stated that the total operating cost of Vistogard™ is $75,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving Vistogard™ is $37,500.

With regard to the newness criterion for the Vistogard™, we considered the beginning of the newness period to commence upon the entry of Vistogard™ onto the U.S. market on March 2, 2016. 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 Vistogard™ onto the U.S. market (March 2, 2019) will occur in the first half of FY 2019, we are proposing to discontinue new technology add-on payments for this technology for FY 2019. We are inviting public comments on our proposal to discontinue new technology add-on payments for the Vistogard™.

g. Bezlotoxumab (ZINPLAVA™)

Merck & Co., Inc. submitted an application for new technology add-on payments for ZINPLAVA™ for FY 2018. ZINPLAVA™ is indicated to reduce recurrence of *Clostridium difficile* infection (CDI) in adult patients who are receiving antibacterial drug treatment for a diagnosis of CDI who are at high risk for CDI recurrence. ZINPLAVA™ is not indicated for the treatment of the presenting episode of CDI and is not an antibacterial drug.

Clostridium difficile (*C-diff*) is a disease-causing anaerobic, spore forming bacteria that can affect the gastrointestinal (GI) tract. Some people carry the *C-diff* bacterium in their intestines, but never develop symptoms of an infection. The difference between asymptomatic colonization and pathogenicity is caused primarily by the production of an enterotoxin (Toxin A) and/or a cytotoxin (Toxin B). The presence of either or both toxins can lead to symptomatic CDI, which is defined as the acute onset of diarrhea with a documented infection with toxigenic *C-diff,* or the presence of either toxin A or B. The GI tract contains millions of bacteria, commonly referred to as ''normal flora'' or ''good

bacteria,'' which play a role in protecting the body from infection. Antibiotics can kill these good bacteria and allow the *C-diff* bacteria to multiply and release toxins that damage the cells lining the intestinal wall, resulting in a CDI. CDI is a leading cause of hospital-associated gastrointestinal illnesses. Persons at increased risk for CDI include people who are treated with current or recent antibiotic use, people who have encountered current or recent hospitalization, people who are older than 65 years, immunocompromised patients, and people who have recently had a diagnosis of CDI. CDI symptoms include, but are not limited to, diarrhea, abdominal pain, and fever. CDI symptoms range in severity from mild (abdominal discomfort, loose stools) to severe (profuse, watery diarrhea, severe pain, and high fevers). Severe CDI can be life-threatening and, in rare cases, can cause bowel rupture, sepsis and organ failure. CDI is responsible for 14,000 deaths per year in the United States.

C-diff produces two virulent, pro-inflammatory toxins, Toxin A and Toxin B, which target host colonocytes (that is, large intestine endothelial cells) by binding to endothelial cell surface receptors via combined repetitive oligopeptide (CROP) domains. These toxins cause the release of inflammatory cytokines leading to intestinal fluid secretion and intestinal inflammation. The applicant asserted that ZINPLAVA™ targets Toxin B sites within the CROP domain rather than the *C-diff* organism itself. According to the applicant, by targeting *C-diff* Toxin B, ZINPLAVA™ neutralizes Toxin B, prevents large intestine endothelial cell inflammation, symptoms associated with CDI, and reduces the recurrence of CDI.

ZINPLAVA™ received FDA approval on October 21, 2016, for reduction of recurrence of CDI in patients receiving antibacterial drug treatment for CDI and who are at high risk of CDI recurrence. ZINPLAVA™ became commercially available on February 10, 2017. Therefore, the newness period for ZINPLAVA™ began on February 10, 2017. The applicant submitted a request for a unique ICD–10–PCS procedure code and was granted approval for the following procedure codes: XW033A3 (Introduction of bezlotoxumab monoclonal antibody, into peripheral vein, percutaneous approach, new technology group 3) and XW043A3 (Introduction of bezlotoxumab monoclonal antibody, into central vein, percutaneous approach, new technology group 3).

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for ZINPLAVA™ and consideration of the public comments we received in response to the FY 2018 IPPS/LTCH PPS proposed rule, we approved ZINPLAVA™ for new technology add-on payments for FY 2018 (82 FR 38119). With the new technology add-on payment application, the applicant estimated that the average Medicare beneficiary would require a dosage of 10 mg/kg of ZINPLAVA™ administered as an IV infusion over 60 minutes as a single dose. According to the applicant, the WAC for one dose is $3,800. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of ZINPLAVA™ is $1,900.

With regard to the newness criterion for ZINPLAVA™, we considered the beginning of the newness period to commence on February 10, 2017. Because the 3-year anniversary date of the entry of ZINPLAVA™ onto the U.S. market (February 10, 2020) will occur after FY 2019, we are proposing to continue new technology add-on payments for this technology for FY 2019. We are proposing that the maximum payment for a case involving ZINPLAVA™ would remain at $1,900 for FY 2019. We are inviting public comments on our proposal to continue new technology add-on payments for ZINPLAVA™ for FY 2019.

5. FY 2019 Applications for New Technology Add-On Payments

We received 15 applications for new technology add-on payments for FY 2019. In accordance with the regulations under § 412.87(c), 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 that the application is being considered. A discussion of the 15 applications is presented below.

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). We note that KYMRIAH™ was approved by the FDA on August 30, 2017, for use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse, which is a different indication and patient population than the new indication and targeted patient population for which the applicant submitted a request for approval of new technology add-on payments for FY 2019. Specifically, and as summarized in the following table, the new indication for which Novartis Pharmaceuticals Corporation is requesting approval for new technology add-on payments for KYMRIAH™ is as an autologous T-cell immune therapy indicated for use in the treatment of patients with relapsed/refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) not eligible for autologous stem cell transplant (ASCT). As of the time of the development of this proposed rule, Novartis Pharmaceuticals Corporation has been granted a Breakthrough Therapy designation by the FDA, and is awaiting FDA approval for the use of KYMRIAH™ under this new indication. We also note that Kite Pharma, Inc. previously submitted an application for approval for new technology add-on payments for FY 2018 for KTE–C19 for use as an autologous T-cell immune therapy in the treatment of adult patients with R/R aggressive B-cell NHL who are ineligible for ASCT. However, Kite Pharma, Inc. withdrew its application for KTE–C19 prior to publication of the FY 2018 IPPS/LTCH PPS final rule. Kite Pharma, Inc. has resubmitted an application for approval for new technology add-on payments for FY 2019 for KTE–C19 under a new name, YESCARTA™, for the same indication. Kite Pharma, Inc. received FDA approval for this original indication and treatment use of YESCARTA™ on October 18, 2017. (We refer readers to the following table for a comparison of the indications and FDA approvals for KYMRIAH™ and YESCARTA™.)

COMPARISON OF INDICATION AND FDA APPROVAL FOR KYMRIAH™ AND YESCARTA™

FY 2019 applicant technology name	Description of indication for which new technology add-on payments are being requested	FDA approval status
KYMRIAH™ (Novartis Pharmaceuticals Corporation).	KYMRIAH™: Autologous T-cell immune therapy indicated for use in the treatment of patients with relapsed/refractory (R/R) Diffuse Large B Cell Lymphoma (DLBCL) not eligible for autologous stem cell transplant (ASCT).	Breakthrough Therapy designation granted by FDA; FDA approval pending.
YESCARTA™ (Kite Pharma, Inc.).	YESCARTA™: Autologous T-cell immune therapy indicated for use in 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, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.	FDA approval received 10/18/2017.

Technology approved for other indications	Description of other indication	FDA approval of other indication
KYMRIAH™ (Novartis Pharmaceuticals Corporation).	KYMRIAH™: CD–19-directed T-cell immunotherapy indicated for the use in the treatment of patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse.	FDA approval received 8/30/2017.
YESCARTA™ (Kite Pharma, Inc.).	None	N/A.

We note that procedures involving the KYMRIAH™ and YESCARTA™ therapies are both 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). We further note that, in section II.F.2.d. of the preamble of this proposed rule, we are proposing to assign cases reporting these ICD–10–PCS procedure codes to Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) for FY 2019. We refer readers to section II.F.2.d. of this proposed rule for a complete discussion of the proposed assignment of cases reporting these procedure codes to Pre-MDC MS–DRG 016, which also includes a proposal to revise the title of MS–DRG 016 to reflect the proposed assignments.

According to the applicants, patients with NHL represent a heterogeneous group of B-cell malignancies with varying patterns of behavior and response to treatment. B-cell NHL can be classified as either an aggressive, or indolent disease, with aggressive variants including DLBCL; primary mediastinal large B-cell lymphoma (PMBCL); and transformed follicular lymphoma (TFL). Within diagnoses of NHL, DLBCL is the most common subtype of NHL, accounting for approximately 30 percent of patients who have been diagnosed with NHL, and survival without treatment is measured in months.[4] Despite improved therapies, only 50 to 70 percent of newly diagnosed patients are cured by standard first-line therapy alone. Furthermore, R/R disease continues to carry a poor prognosis because only 50 percent of patients are eligible for autologous stem cell transplantation (ASCT) due to advanced age, poor functional status, comorbidities, inadequate social support for recovery after ASCT, and provider or patient choice.[5] [6] [7] [8] Of the roughly 50 percent of patients that are eligible for ASCT, nearly 50 percent fail to respond to prerequisite salvage chemotherapy and cannot undergo ASCT.[9] [10] [11] [12] Second-line chemotherapy regimens studied to date include rituximab, ifosfamide, carboplatin and etoposide (R–ICE), and rituximab, dexamethasone, cytarabine, and cisplatin (R–DHAP), followed by consolidative high-dose therapy (HDT)/ASCT. Both regimens offer similar overall response rates (ORR) of 51 percent with 1 in 4 patients achieving long-term complete response (CR) at the expense of increased toxicity.[13] Second-line treatment with dexamethasone, high-dose cytarabine, and cisplatin (DHAP) is considered a standard chemotherapy regimen, but is associated with substantial treatment-related toxicity.[14] For patients who experience disease progression during or after primary treatment, the combination of HDT/ASCT remains the only curative option.[15] According to the applicants,

[4] Chaganti, S., et al., ''Guidelines for the management of diffuse large B-cell lymphoma,'' BJH Guideline, 2016. Available at: *www.bit.do/bsh-guidelines.*

[5] Matasar, M., et al., ''Ofatumumab in combination with ICE or DHAP chemotherapy in relapsed or refractory intermediate grade B-cell lymphoma,'' *Blood,* 25 July 2013, vol. 122, No 4.

[6] Hitz, F., et al., ''Outcome of patients with chemotherapy refractory and early progressive diffuse large B cell lymphoma after R–CHOP treatment,'' *Blood* (American Society of Hematology (ASH) annual meeting abstracts, poster session), 2010, pp. 116 (abstract #1751).

[7] Telio, D., et al., ''Salvage chemotherapy and autologous stem cell transplant in primary refractory diffuse large B-cell lymphoma: outcomes and prognostic factors,'' *Leukemia & Lymphoma,* 2012, vol. 53(5), pp. 836–41.

[8] Moskowitz, C.H., et al., ''Ifosfamide, carboplatin, and etoposide: a highly effective cytoreduction and peripheral-blood progenitor-cell mobilization regimen for transplant-eligible patients with non-Hodgkin's lymphoma,'' *Journal of Clinical Oncology,* 1999, vol. 17(12), pp. 3776–85.

[9] Crump, M., et al., ''Outcomes in patients with refractory aggressive diffuse large B-cell lymphoma (DLBCL): results from the international scholar-1 study,'' Abstract and poster presented at Pan Pacific Lymphoma Conference (PPLC), July 2016.

[10] Gisselbrecht, C., et al., ''Results from SCHOLAR–1: outcomes in patients with refractory aggressive diffuse large B-cell lymphoma (DLBCL),'' Oral presentation at European Hematology Association conference, July 2016.

[11] Iams, W., Reddy, N., ''Consolidative autologous hematopoietic stem-cell transplantation in first remission for non-Hodgkin lymphoma: current indications and future perspective,'' *Ther Adv Hematol,* 2014, vol. 5(5), pp. 153–67.

[12] Kantoff, P.W., et al., ''Sipuleucel-T immunotherapy for castration-resistant prostate cancer,'' *N Engl J Med,* 2010, vol. 363, pp. 411–422.

[13] Rovira, J., Valera, A., Colomo, L., et al., ''Prognosis of patients with diffuse large B cell lymphoma not reaching complete response or relapsing after frontline chemotherapy or immunochemotherapy,'' *Ann Hematol,* 2015, vol. 94(5), pp. 803–812.

[14] Swerdlow, S.H., Campo, E., Pileri, S.A., et al., ''The 2016 revision of the World Health Organization classification of lymphoid neoplasms,'' *Blood,* 2016, vol. 127(20), pp. 2375–2390.

[15] Koristka, S., Cartellieri, M., Arndt, C., et al., ''Tregs activated by bispecific antibodies: killers or

Continued

given the modest response to second-line therapy and/or HDT/ASCT, the population of patients with the highest unmet need is those with chemorefractory disease, which include DLBCL, PMBCL, and TFL. These patients are defined as either progressive disease (PD) as best response to chemotherapy, stable disease as best response following greater than or equal to 4 cycles of first-line or 2 cycles of later-line therapy, or relapse within less than or equal to 12 months of ASCT.[16] Based on these definitions and available data from a multi-center retrospective study (SCHOLAR–1), chemorefractory disease treated with current and historical standards of care has consistently poor outcomes with an ORR of 26 percent and median overall survival (OS) of 6.3 months.[17]

According to Novartis Pharmaceuticals Corporation, upon FDA approval of the additional indication, KYMRIAH™ will also be used for the treatment of patients with R/R DLBCL who are not eligible for ASCT. Novartis Pharmaceuticals Corporation describes KYMRIAH™ as a CD-19-directed genetically modified autologous T-cell immunotherapy which utilizes peripheral blood T-cells, which have been reprogrammed with a transgene encoding, a chimeric antigen receptor (CAR), to identify and eliminate CD–19-expressing malignant and normal cells. Upon binding to CD–19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of KYMRIAH™ cells. The transduced T-cells expand in vivo to engage and eliminate CD–19-expressing cells and may exhibit immunological endurance to help support long-lasting remission.[18] [19] [20] [21] According to the applicant, no other agent currently used in the treatment of patients with R/R DLBCL employs gene modified autologous cells to target and eliminate malignant cells.

According to Kite Pharma, Inc., YESCARTA™ is indicated for the use in 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, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma. The applicant for YESCARTA™ described the technology as a CD–19-directed genetically modified autologous T-cell immunotherapy that binds to CD–19-expressing cancer cells and normal B-cells. These normal B-cells are considered to be non-essential tissue, as they are not required for patient survival. According to the applicant, studies demonstrated that following anti-CD–19 CAR T-cell engagement with CD–19-expressing target cells, the CD–28 and CD–3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to the elimination of CD–19-expressing tumor cells.

Both applicants expressed that their technology is the first treatment of its kind for the targeted adult population. In addition, both applicants asserted that their technology is new and does not use a substantially similar mechanism of action or involve the same treatment indication as any other currently FDA-approved technology. We note that, at the time each applicant submitted its new technology add-on payment application, neither technology had received FDA approval for the indication for which the applicant requested approval for the new technology add-on payment; KYMRIAH™ has been granted Breakthrough Therapy designation for the use in the treatment of patients for the additional indication that is the subject of its new technology add-on application and, as of the time of the development of this proposed rule, is awaiting FDA approval. However, as stated earlier, YESCARTA™ received FDA approval for use in the treatment of patients and the indication stated in its application on October 18, 2017, after each applicant submitted its new technology add-on payment application.

As noted, according to both applicants, KYMRIAH™ and YESCARTA™ are the first CAR T immunotherapies of their kind. 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 we believe 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 disagree with the applicants and believe these two technologies are substantially similar to each other and that it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. For these reasons, and as discussed further below, we would intend to make one determination regarding approval for new technology add-on payments that would apply to both applications, and in accordance with our policy, would use the earliest market availability date submitted as the beginning of the newness period for both KYMRIAH™ and YESCARTA™. We are inviting public comments on whether KYMRIAH™ and YESCARTA™ are substantially similar.

With respect to the newness criterion, as previously stated, YESCARTA™ received FDA approval on October 18, 2017. According to the applicant, prior to FDA approval, YESCARTA™ had been available in the U.S. only on an investigational basis under an investigational new drug (IND) application. For the same IND patient population, and until commercial availability, YESCARTA™ was available under an Expanded Access Program (EAP) which started on May 17, 2017. The applicant stated that it did not recover any costs associated with the EAP. According to the applicant, the first commercial shipment of YESCARTA™ was received by a certified treatment center on November 22, 2017. As previously indicated, KYMRIAH™ is not currently approved by the FDA for use in the treatment of patients with R/R DLBCL that are not eligible for ASCT; the technology has been granted Breakthrough Therapy designation by the FDA. The applicant anticipates receipt of FDA approval to occur in the second quarter of 2018. We believe that, in accordance with our policy, if these technologies are 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. Therefore, based on

suppressors?,'' *OncoImmunology,* 2015, vol. (3):e994441, DOI: 10.4161/2162402X.2014.994441.

[16] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood-2017-03-69620.

[17] Ibid.

[18] KYMRIAH™ [prescribing information], East Hanover, NJ: Novartis Pharmaceuticals Corp, 2017.

[19] Kalos, M., Levine, B.L., Porter, D.L., 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, vol. 3(95), pp, 95ra73.

[20] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[21] Wang, X., Riviere, I., ''Clinical manufacturing of CART cells: foundation of a promising therapy,'' *Mol Ther Oncolytics,* 2016, vol. 3, pp. 16015.

our policy, with regard to both technologies, if the technologies are approved for new technology add-on payments, we believe that the beginning of the newness period would be November 22, 2017.

We previously stated that, because we believe these two technologies are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discuss each set of data separately. However, we would intend to make one determination regarding new technology add-on payments that would apply to both applications. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and we believe that continuing our current practice of extending new technology add-on payments without a further application from the manufacturer of the competing product, or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products to submit separate new technology add-on payment applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

If substantially similar technologies are submitted for review in different (and subsequent) years, rather than the same year, we would evaluate and make a determination on the first application and apply that same determination to the second application. However, because the technologies have been submitted for review in the same year, and because we believe they are substantially similar to each other, we believe that it is appropriate to consider both sets of cost data and clinical data in making a determination, and we do not believe that it is possible to choose one set of data over another set of data in an objective manner. We are inviting public comments on our proposal to evaluate KYMRIAH™ and YESCARTA™ as one application for new technology add-on payments under the IPPS.

As stated earlier, we believe that KYMRIAH™ and YESCARTA™ are substantially similar to each other for purposes of analyzing these two applications as one application. We also need to determine whether KYMRIAH™ and YESCARTA™ are substantially similar to existing technologies prior to their approval by the FDA and their release onto the U.S. market. 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 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 for KYMRIAH™ asserted that its unique design, which utilizes features that were not previously included in traditional cytotoxic chemotherapeutic or immunotherapeutic agents, constitutes a new mechanism of action. The deployment mechanism allows for identification and elimination of CD–19-expressing malignant and non-malignant cells, as well as possible immunological endurance to help support long-lasting remission.[22] [23] [24] [25] The applicant provided context regarding how KYMRIAH™'s unique design contributes to a new mechanism of action by explaining that peripheral blood T-cells, which have been reprogrammed with a transgene encoding, a CAR, identify and eliminate CD-19-expressing malignant and nonmalignant cells. As explained by the applicant, upon binding to CD–19-expressing cells, the CAR transmits a signal to promote T-cell expansion, activation, target cell elimination, and persistence of KYMRIAH™ cells.[26] [27] [28] According to the applicant, transduced T-cells expand in vivo to engage and eliminate CD–19-expressing cells and may exhibit immunological endurance to help support long-lasting remission.[29] [30] [31]

The applicant for YESCARTA™ stated that YESCARTA™ is the first engineered autologous cellular immunotherapy comprised of CAR T-cells that recognizes CD–19 express cancer cells and normal B-cells with efficacy in patients with R/R large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma as demonstrated in a multi-centered clinical trial. Therefore, the applicant believed that YESCARTA™'s mechanism of action is distinct and unique from any other cancer drug or biologic that is currently approved for use in the treatment of patients who have been diagnosed with aggressive B-cell NHL, namely single-agent or combination chemotherapy regimens. The applicant also pointed out that YESCARTA™ is the only available therapy that has been granted FDA approval 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, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

With respect to the second and third criteria, whether a product is assigned to the same or a different MS–DRG and 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 for KYMRIAH™ indicated that the technology is used in the treatment of the same patient population, and potential cases representing patients that may be eligible for treatment using KYMRIAH™ would be assigned to the same MS–DRGs as cases involving

[22] KYMRIAH [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2017.

[23] Kalos, M., Levine, B.L., Porter, D.L., 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, vol. 3(95), pp. 95ra73.

[24] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[25] Maude, S.L., Frey, N., Shaw, P.A., et al., ''Chimeric antigen receptor T cells for sustained remissions in leukemia,'' *N Engl J Med,* 2014, vol. 371(16), pp. 1507–1517.

[26] KYMRIAH™ [prescribing information], East Hanover, NJ: Novartis Pharmaceuticals Corp, 2017.

[27] Kalos, M., Levine, B.L., Porter, D.L., 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), pp, 95ra73.

[28] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[29] Kalos, M., Levine, B.L., Porter, D.L., 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, vol. 3(95), pp. 95rs73.

[30] FDA Briefing Document. Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566168.pdf.*

[31] Maude, S.L., Frey, N., Shaw, P.A., et al., ''Chimeric antigen receptor T-cells for sustained remissions in leukemia,'' *N Engl J Med,* 2014, vol. 371(16), pp. 1507–1517.

patients with a DLBCL diagnosis. Potential cases representing patients that may be eligible for treatment using KYMRIAH™ map to 437 separate MS–DRGs, with the top 20 MS–DRGs covering approximately 68 percent of all patients who have been diagnosed with DLBCL. For patients with DLBCL and who have received chemotherapy during their hospital stay, the target population mapped to 8 separate MS–DRGs, with the top 2 MS–DRGs covering over 95 percent of this population: MS–DRGs 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC), and 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC). The applicant for YESCARTA™ submitted findings that potential cases representing patients that may be eligible for treatment using YESCARTA™ span 15 unique MS–DRGs, 8 of which contain more than 10 cases. The most common MS–DRGs were: MS–DRGs 840 (Lymphoma and Non-Acute Leukemia with MCC), 841 (Lymphoma and Non-Acute Leukemia with CC), and 823 (Lymphoma and Non-Acute Leukemia with other O.R. Procedures with MCC). These 3 MS–DRGs accounted for 628 (76 percent) of the 827 cases. While the applicants for KYMRIAH™ and YESCARTA™ submitted different findings regarding the most common MS–DRGs to which potential cases representing patients who may be eligible for treatment involving their technology would map, we believe that, under the current MS–DRGs (FY 2018), potential cases representing patients who may be eligible for treatment involving either KYMRIAH™ or YESCARTA™ would map to the same MS–DRGs because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes would be used to report cases for patients who may be eligible for treatment involving KYMRIAH™ and YESCARTA™. Furthermore, as noted above, we are proposing that cases reporting these ICD–10–PCS procedure codes would be assigned to MS–DRG 016 for FY 2019. Therefore, under this proposal, for FY 2019, cases involving the utilization of KYMRIAH™ and YESCARTA™ would continue to map to the same MS–DRGs.

The applicant for YESCARTA™ also addressed the concern expressed by CMS in the FY 2018 IPPS/LTCH PPS proposed rule regarding Kite Pharma Inc.'s FY 2018 new technology add-on payment application for the KTE–C19 technology (82 FR 19888). At the time, CMS expressed concern that KTE–C19 may use the same or similar mechanism of action as the Bi-Specific T-Cell engagers (BiTE) technology. The applicant for YESCARTA™ explained that YESCARTA™ has a unique and distinct mechanism of action that is substantially different from BiTE's or any other drug or biologic currently assigned to any MS–DRG in the FY 2016 MedPAR Hospital Limited Data Set. In providing more detail regarding how YESCARTA™ is different from the BiTE technology, the applicant explained that the BiTE technology is not an engineered autologous T-cell immunotherapy derived from a patient's own T-cells. Instead, it is a bi-specific T-cell engager that recognizes CD–19 and CD–3 cancer cells. Unlike engineered T-cell therapy, BiTE does not have the ability to enhance the proliferative and cytolytic capacity of T-cells through ex-vivo engineering. Further, BiTE is approved for the treatment of patients who have been diagnosed with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and is not approved for patients with relapsed or refractory large B-cell lymphoma, whereas YESCARTA™ is indicated for use in the treatment of adult patients with R/R aggressive B-cell NHL who are ineligible for ASCT.

The applicant for YESCARTA™ also indicated that its mechanism of action is not the same or similar to the mechanism of action used by KYMRIAH™'s currently available FDA-approved CD–19-directed genetically modified autologous T-cell immunotherapy indicated for use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.[32] The applicant for YESCARTA™ stated that the mechanism of action is different from KYMRIAH™'s FDA-approved therapy because the spacer, transmembrane and co-stimulatory domains of YESCARTA™ are different from those of KYMRIAH™. The applicant explained that YESCARTA™ is comprised of a CD–28 co-stimulatory domain and KYMRIAH™ has 4–1BB co-stimulatory domain. Further, the applicant stated the manufacturing processes of the two immunotherapies are also different, which may result in cell composition differences leading to possible efficacy and safety differences.

While the applicant for YESCARTA™ stated how its technology is different from KYMRIAH™, because both technologies are CD–19-directed T-cell immunotherapies used for the purpose of treating patients with aggressive variants of NHL, we believe that YESCARTA™ and KYMRIAH™ are substantially similar treatment options. Furthermore, we also are concerned that there may be an age overlap (18 to 25) between the two different patient populations for the currently approved KYMRIAH™ technology and YESCARTA™ technology. The currently approved KYMRIAH™ technology is indicated for use in the treatment of patients who are up to 25 years of age and YESCARTA™ technology is indicated for use in the treatment of adult patients.

As noted earlier, the applicant has asserted that YESCARTA™ is not substantially similar to KYMRIAH™. Under this scenario, if both YESCARTA™ and KYMRIAH™ meet all of the new technology add-on payment criteria and are approved for new technology add-on payments for FY 2019, for purposes of making the new technology add-on payment, because procedures utilizing either YESCARTA™ or KYMRIAH™ CAR T-cell therapy drugs are reported using the same ICD–10–PCS procedure codes, in order to accurately pay the new technology add-on payment to hospitals that perform procedures utilizing either technology, it may be necessary to use alternative coding mechanisms to make the new technology add-on payments. CMS is inviting comments on alternative coding mechanisms to make the new technology add-on payments, if necessary.

We are inviting public comments on whether KYMRIAH™ and YESCARTA™ are substantially similar to existing technologies and whether the technologies meet the newness criterion.

As we stated above, each applicant submitted separate analysis regarding the cost criterion for each of their products, and both applicants maintained that their product meets the cost criterion. We summarize each analysis below.

With regard to the cost criterion, the applicant for KYMRIAH™ searched the FY 2016 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment using KYMRIAH™. 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

[32] Food and Drug Administration. Available at: *www.accessdata.fda.gov/scripts/opdlisting/oopd/.*

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). The applicant also identified potential cases where patients received chemotherapy using two encounter codes, Z51.11 (Antineoplastic chemotherapy) and Z51.12 (Antineoplastic immunotherapy), in conjunction with DLBCL diagnosis codes.

Applying the parameters above, the applicant for KYMRIAH™ identified a total of 22,589 DLBCL potential cases that mapped to 437 MS–DRGs. The applicant chose the top 20 MS–DRGs which made up a total of 15,451 potential cases at 68 percent of total cases. Of the 22,589 total DLBCL potential cases, the applicant also provided a breakdown of DLBCL potential cases where chemotherapy was used, and DLBCL potential cases where chemotherapy was not used. Of the 6,501 DLBCL potential cases where chemotherapy was used, MS–DRGs 846 and 847 accounted for 6,181 (95 percent) of the 6,501 cases. Of the 16,088 DLBCL potential cases where chemotherapy was not used, the applicant chose the top 20 MS–DRGs which made up a total of 9,333 potential cases at 58 percent of total cases. The applicant believed the distribution of patients that may be eligible for treatment using KYMRIAH™ will include a wide variety of MS–DRGs. As such, the applicant conducted an analysis of three scenarios: Potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy.

The applicant removed reported historic charges that would be avoided through the use of KYMRIAH™. Next, the applicant removed 50 percent of the chemotherapy pharmacy charges that would not be required for patients that may be eligible to receive treatment using KYMRIAH™. The applicant standardized the charges and then applied an inflation factor of 1.09357, which is the 2-year inflation factor in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527), to update the charges from FY 2016 to FY 2018. The applicant did not add charges for KYMRIAH™ to its analysis. However, the applicant provided a cost analysis related to the three categories of claims data it previously researched (that is, potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy). The applicant's analysis showed the inflated average case-weighted standardized charge per case for potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy was $63,271, $39,723, and $72,781, respectively. The average case-weighted threshold amount for potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy was $58,278, $48,190, and $62,355 respectively. While the inflated average case-weighted standardized charge per case ($39,723) is lower than the average case-weighted threshold amount ($48,190) for potential DLBCL cases with chemotherapy, the applicant expects the cost of KYMRIAH™ to be higher than the new technology add-on payment threshold amount for all three cohorts. Therefore, the applicant maintained that it meets the cost criterion.

We note that, as discussed earlier, in section II.F.2.d. of the preamble of this proposed rule, we are proposing to assign the ICD–10–PCS procedure codes that describe procedures involving the utilization of these CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy procedures to Pre-MDC MS–DRG 016 for FY 2019. Therefore, in addition to the analysis above, we compared the inflated average case-weighted standardized charge per case from all three cohorts above to the average case-weighted threshold amount for MS–DRG 016. The average case-weighted threshold amount for MS–DRG 016 from Table 10 in the FY 2018 IPPS/LTCH PPS final rule is $161,058. Although the inflated average case-weighted standardized charge per case for all three cohorts ($63,271, $39,723, and $72,781) is lower than the average case-weighted threshold amount for MS–DRG 016, similar to above, the applicant expects the cost of KYMRIAH™ to be higher than the new technology add-on payment threshold amount for MS–DRG 016. Therefore, it appears that KYMRIAH™ would meet the cost criterion under this scenario as well.

We appreciate the applicant's analysis. However, we note that the applicant did not provide information regarding which specific historic charges were removed in conducting its cost analysis. Nonetheless, we believe that even if historic charges were identified and removed, the applicant would meet the cost criterion because, as indicated, the applicant expects the cost of KYMRIAH™ to be higher than the new technology add-on payment threshold amounts listed earlier.

We are inviting public comments on whether KYMRIAH™ meets the cost criterion.

With regard to the cost criterion in reference to YESCARTA™, the applicant conducted the following analysis. The applicant examined FY 2016 MedPAR claims data restricted to patients discharged in FY 2016. The applicant included potential cases reporting an ICD–10 diagnosis code of C83.38. Noting that only MS–DRGs 820 (Lymphoma and Leukemia with Major O.R. Procedure with MCC), 821 (Lymphoma and Leukemia with Major O.R. Procedure with CC), 823 and 824 (Lymphoma and Non-Acute Leukemia with Other O.R. Procedure with MCC, with CC, respectively), 825 (Lymphoma and Non Acute Leukemia with Other O.R Procedure without CC/MCC), and 840, 841 and 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC and without CC/MCC, respectively) consisted of 10 or more cases, the applicant limited its analysis to these 8 MS–DRGs. The applicant identified 827 potential cases across these MS–DRGs. The average case-weighted unstandardized charge per case was $126,978. The applicant standardized charges using FY 2016 standardization factors and applied an inflation factor of 1.09357 from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527). The applicant for YESCARTA™ did not include the cost of its technology in its analysis.

Included in the average case-weighted standardized charge per case were charges for the current treatment components. Therefore, the applicant for YESCARTA™ removed 20 percent of radiology charges to account for chemotherapy, and calculated the adjusted average case-weighted standardized charge per case by subtracting these charges from the standardized charge per case. Based on the distribution of potential cases within the eight MS–DRGs, the applicant case-weighted the final inflated average case-weighted standardized charge per case. This resulted in an inflated average case-weighted standardized charge per case of $118,575. Using the FY 2018 IPPS Table 10 thresholds, the average case-weighted threshold amount was $72,858. Even without considering the cost of its technology, the applicant maintained that because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the technology meets the cost criterion.

We note that, as discussed earlier, in section II.F.2.d. of the preamble of this proposed rule, we are proposing to assign the ICD–10–PCS procedure codes that describe procedures involving the utilization of these CAR T-cell therapy

drugs and cases representing patients receiving treatment involving CAR T-cell therapy procedures to Pre-MDC MS–DRG 016 for FY 2019. Therefore, in addition to the analysis above, we compared the inflated average case-weighted standardized charge per case ($118,575) to the average case-weighted threshold amount for MS–DRG 016. The average case-weighted threshold amount for MS–DRG 016 from Table 10 in the FY 2018 IPPS/LTCH PPS final rule is $161,058. Although the inflated average case-weighted standardized charge per case is lower than the average case-weighted threshold amount for MS–DRG 016, the applicant expects the cost of YESCARTA™ to be higher than the new technology add-on payment threshold amount for MS–DRG 016. Therefore, it appears that YESCARTA™ would meet the cost criterion under this scenario as well.

We are inviting public comments on whether YESCARTA™ technology meets the cost criterion.

With regard to substantial clinical improvement for KYMRIAH™, the applicant asserted that several aspects of the treatment represent a substantial clinical improvement over existing technologies. The applicant believed that KYMRIAH™ allows access for a treatment option for those patients who are unable to receive standard of care treatment. The applicant stated in its application that there are no currently FDA-approved treatment options for patients with R/R DLBCL who are ineligible for or who have failed ASCT. Additionally, the applicant maintained that KYMRIAH™ significantly improves clinical outcomes, including ORR, CR, OS, and durability of response, and allows for a manageable safety profile. The applicant asserted that, when compared to the historical control data (SCHOLAR–1) and the currently available treatment options, it is clear that KYMRIAH™ significantly improves clinical outcomes for patients with R/R DLBCL who are not eligible for ASCT. The applicant conveyed that, given that the patient population has no other available treatment options and an expected very short lifespan without therapy, there are no randomized controlled trials of the use of KYMRIAH™ in patients with R/R DLBCL and, therefore, efficacy assessments must be made in comparison to historical control data. The SCHOLAR–1 study is the most comprehensive evaluation of the outcome of patients with refractory DLBCL. SCHOLAR–1 includes patients from two large randomized controlled trials (Lymphoma Academic Research Organization-CORAL and Canadian Cancer Trials Group LY.12) and two clinical databases (MD Anderson Cancer Center and University of Iowa/Mayo Clinic Lymphoma Specialized Program of Research Excellence).[33]

The applicant for KYMRIAH™ conveyed that the PARMA study established high-dose chemotherapy and ASCT as the standard treatment for patients with R/R DLBCL.[34] However, according to the applicant, many patients with R/R DLBCL are ineligible for ASCT because of medical frailty. Patients who are ineligible for ASCT because of medical frailty would also be adversely affected by high-dose chemotherapy regimens.[35] Lowering the toxicity of chemotherapy regimens becomes the only treatment option, leaving patients with little potential for therapeutic outcomes. According to the applicant, the lack of efficacy of these aforementioned salvage regimens was demonstrated in nine studies evaluating combined chemotherapeutic regimens in patients who were either refractory to first-line or first salvage. Chemotherapy response rates ranged from 0 percent to 23 percent with OS less than 10 months in all studies.[36] For patients who do not respond to combined therapy regimens, the National Comprehensive Cancer Network (NCCN) offers only clinical trials or palliative care as therapeutic options.[37]

According to the applicant for KYMRIAH™, the immunomodulatory agent Lenalidomide was only able to show an ORR of 30 percent, a CR rate of 8 percent, and a 4.6-month median duration of response.[38] M-tor inhibitors such as Everolimus and Temserolimus have been studied as single agents, or in combination with Rituximab, as have newer monoclonal antibodies Dacetuzumab, Ofatumomab and Obinutuzumab. However, none induced a CR rate higher than 20 percent or showed a median duration of response longer than 1 year.[39]

According to the applicant, although controversial, allogeneic stem cell transplantation (allo-SCT) has been proposed for patients who have been diagnosed with R/R disease. It is hypothesized that the malignant cell will be less able to escape the immune targeting of allogenic T-cells—known as the graft-vs-lymphoma effect.[40] [41] The use of allo-SCT is limited in patients who are not eligible for ASCT because of the high rate of morbidity and mortality. This medically frail population is generally excluded from participation. The population most impacted by this is the elderly, who are often excluded based on age alone. In seven studies evaluating allo-SCT in patients with R/R DLBCL, the median age at transplant was 43 years old to 52 years old, considerably lower than the median age of patients with DLBCL of 64 years old. Only two studies included any patients over 66 years old. In these studies, allo-SCT provided OS rates ranging from 18 percent to 52 percent at 3 to 5 years, but was accompanied by treatment-related mortality rates ranging from 23 percent to 56 percent.[42] According to the applicant, this toxicity and efficacy profile of allo-SCT substantially limits its use, especially in patients 65 years old and older. Given the high unmet medical need, the applicant maintained that KYMRIAH™ represents a substantial clinical improvement by offering a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

To express how KYMRIAH™ has improved clinical outcomes, including ORR, CR rate, OS, and durability of response, the applicant referenced clinical trials in which KYMRIAH™ was tested. Study 1 was a single-arm, open-label, multi-site, global Phase II study to determine the safety and efficacy of tisagenlecleucel in patients

[33] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood-2017-03-769620.

[34] Philip, T., Guglielmi, C., Hagenbeek, A., et al., ''Autologous bone marrow transplantation as compared with salvage chemotherapy in relapses of chemotherapy-sensitive non-Hodgkin's lymphoma,'' *N Engl J Med,* 1995, vol. 333(23), pp. 1540–1545.

[35] Friedberg, J.W., ''Relapsed/refractory diffuse large B-cell lymphoma,'' *Hematology AM Soc Hematol Educ Program,* 2011, vol. (1), pp. 498–505.

[36] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood-2017-03-769620.

[37] National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN GuidelinesR), ''B-cell lymphomas: Diffuse large b-cell lymphoma and follicular lymphoma (Version 3.2017),'' May 25, 2017. Available at: *https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf.*

[38] Klyuchnikov, E., Bacher, U., Kroll, T., et al., ''Allogeneic hematopoietic cell transplantation for diffuse large B cell lymphoma: who, when and how?,'' *Bone Marrow Transplant,* 2014, vol. 49(1), pp. 1–7.

[39] Ibid.

[40] Ibid.

[41] Maude, S.L., Teachey, D.T., Porter, D.L., Grupp, S.A., ''CD19-targeted chimeric antigen receptor T-cell therapy for acute lymphoblastic leukemia,'' *Blood,* 2015, vol. 125(26), pp. 4017–4023.

[42] Klyuchnikov, E., Bacher, U., Kroll, T., et al., ''Allogeneic hematopoietic cell transplantation for diffuse large B cell lymphoma: who, when and how?,'' *Bone Marrow Transplant,* 2014, vol. 49(1), pp. 1–7.

with R/R DLBCL (CCTL019C2201/CT02445248/'JULIET' study).[43] [44] [45] Key inclusion criteria included patients who were 18 years old and older, patients with refractory to at least two lines of chemotherapy and either relapsed post ASCT or who were ineligible for ASCT, measurable disease at the time of infusion, and adequate organ and bone marrow function. The study was conducted in three phases. In the screening phase patient eligibility was assessed and patient cells collected for product manufacture. Patients were also able to receive bridging, cytotoxic chemotherapy during this time. In the pre-treatment phase patients underwent a restaging of disease followed by lymphodepleting chemotherapy with fludarabine 25mg/m2 x3 and cyclophosphamide 250mg/m2/d x3 or bendamustine 90mg/m2/d x2 days. The treatment and follow-up phase began 2 to 14 days after lymphodepleting chemotherapy, when the patient received a single infusion of tisagenlecleucel with a target dose of $5x10^8$ CTL019 transduced viable cells. The primary objective was to assess the efficacy of tisagenlecleucel, as measured by the best overall response (BOR), which was defined as CR or partial response (PR). It was assessed on the Chesson 2007 response criteria amended by Novartis Pharmaceutical Corporation as confirmed by an Independent Review Committee (IRC). One hundred forty-seven patients were enrolled, and 99 of them were infused with tisagenlecleucel. Forty-three patients discontinued prior to infusion (9 due to inability to manufacture and 34 due to patient-related issues).[46] The median age of treated patients was 56 years old with a range of 24 to 75; 20 percent were older than 65 years old. Patients had received 2 to 7 prior lines of therapy, with 60 percent receiving 3 or more therapies, and 51 percent having previously undergone ASCT. A primary analysis was performed on 81 patients infused and followed for more than or at least 3 months. In this primary analysis, the BOR was 53 percent; the study met its primary objective based on statistical analysis (that is, testing whether BOR was greater than 20 percent, a clinically relevant threshold chosen based on the response to chemotherapy in a patient with R/R DLBCL). Forty-three percent (43 percent) of evaluated patients reached a CR, and 14 percent reached a PR. ORR evaluated at 3 months was 38 percent with a distribution of 32 percent CR and 6 percent PR. All patients in CR at 3 months continued to be in CR. ORR was similar across subgroups including 64.7 percent response in patients who were older than 65 years old, 61.1 percent response in patients with Grade III/IV disease at the time of enrollment, 58.3 percent response in patients with Activated B-cell, 52.4 percent response in patients with Germinal Center B-cell subtype, and 60 percent response in patients with double and triple hit lymphoma. Durability of response was assessed based on relapse free survival (RFS), which was estimated at 74 percent at 6 months.

The applicant for KYMRIAH™ reported that Study 2 was a supportive Phase IIa single institution study of adults who were diagnosed with advanced CD19+ NHL conducted at the University of Pennsylvania.[47] [48] Tisagenlecleucel cells were produced at the University of Pennsylvania using the same genetic construct and a similar manufacturing technique as employed in Study 1. Key inclusion criteria included patients who were at least 18 years old, patients with CD19+ lymphoma with no available curative options, and measurable disease at the time of enrollment. Tisagenlecleucel was delivered in a single infusion 1 to 4 days after restaging and lymphodepleting chemotherapy. The median tisagenlecleucel cell dose was 5.0×108 transduced cells. The study enrolled 38 patients; of these, 21 were diagnosed with DLBCL and 13 received treatment involving KYMRIAH™. Patients ranged in age from 25 to 77 years old, and had a median of 4 prior therapies. Thirty-seven percent had undergone ASCT and 63 percent were diagnosed with Grade III/IV disease. ORR at 3 months was 54 percent. Progression free survival was 43 percent at a median follow-up of 11.7 months. Safety and efficacy results are similar to those of the multi-center study.

The applicant for KYMRIAH™ reported that Study 3 was a supportive, patient-level meta-analysis of historical outcomes in patients who were diagnosed with refractory DLBCL (SCHOLAR–1).[49] This study included a pooled data analysis of two Phase III clinical trials (Lymphoma Academic Research Organization-CORAL and Canadian Cancer Trials Group LY.12) and two observational cohorts (MD Anderson Cancer Center and University of Iowa/Mayo Clinic Lymphoma Specialized Program of Research Excellence). Refractory disease was defined as progressive disease or stable disease as best response to chemotherapy (received more than or at least 4 cycles of first-line therapy or 2 cycles of later-line therapy, respectively) or relapse in less than or at 12 months post-ASCT. Of 861 abstracted records, 636 were included based on these criteria. All patients from each data source who met criteria for diagnosis of refractory DLBCL, including TFL and PMBCL, who went on to receive subsequent therapy were considered for analysis. Patients who were diagnosed with TFL and PMBCL were included because they are histologically similar and clinically treated as large cell lymphoma. Response rates were similar across the 4 datasets, ranging from 20 percent to 31 percent, with a pooled response rate of 26 percent. CR rates ranged from 2 percent to 15 percent, with a pooled CR rate of 7 percent. Subgroup analyses including patients with primary refractory, refractory to second or later-line therapy, and relapse in less than 12 months post-ASCT revealed response rates similar to the pooled analysis, with worst outcomes in the primary refractory group (20 percent). OS from the commencement of therapy was 6.3 months and was similar across subgroup analyses. Achieving a CR after last salvage chemotherapy predicted a longer OS of 14.9 months compared to 4.6 months in nonresponders. Patients who had not undergone ASCT had an OS of 5.1

[43] Data on file, Oncology clinical trial protocol CCTL019C2201: ''A Phase II, single-arm, multi-center trial to determine the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large Bcell lymphoma (DLBCL),'' Novartis Pharmaceutical Corp, 2015.

[44] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[45] *ClinicalTrials.gov*, ''Study of efficacy and safety of CTL019 in adult DLBCL patients (JULIET).'' Available at: *https://clinicaltrials.gov/ct2/show/NCT02445248.*

[46] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[47] *ClinicalTrials.gov*, ''Phase IIa study of redirected autologous T-cells engineered to contain anti-CD19 attached to TCRz and 4-signaling domains in patients with chemotherapy relapsed or refractory CD19+ lymphomas,'' Available at: *https://clinicaltrials.gov/ct2/show/NCT02030834.*

[48] Schuster, S.J., Svoboda, J., Nasta, S.D., et al., ''Sustained remissions following chimeric antigen receptor modified T-cells directed against CD–19 (CTL019) in patients with relapsed or refractory CD19+ lymphomas,'' Presented at: 57th Annual Meeting of the American Society of Hematology, December 6, 2015, Orlando, FL.

[49] Crump, M., Neelapu, S.S., Farooq, U., et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* Published online: August 3, 2017, doi: 10.1182/blood-2017-03-769620.

months with a 2 year OS rate of 11 percent.

The applicant asserted that KYMRIAH™ provides a manageable safety profile when treatment is performed by trained medical personnel and, as opposed to ASCT, KYMRIAH™ mitigates the need for high-dose chemotherapy to induce response prior to infusion. Adverse events were most common in the 8 weeks following infusion and were manageable by a trained staff. Cytokine Relapse Syndrome (CRS) occurred in 58 percent of patients with 23 percent having Grade III or IV events as graded on the University of Pennsylvania grading system.[50] [51] Median time to onset of CRS was 3 days and median duration was 7 days with a range of 2 to 30 days. Twenty-four percent of the patients required ICU admission. CRS was managed with supportive care in most patients. However, 16 percent required anti-cytokine therapy including tocilizumab (15 percent) and corticosteroids (11 percent). Other adverse events of special interest include infection in 34 percent (20 percent Grade III or IV) of patients, cytopenias not resolved by day 28 in 36 percent (27 percent Grade III or IV) of patients, neurologic events in 21 percent (12 percent Grade III or IV) of patients, febrile neutropenia in 13 percent (13 percent Grade III or IV) of patients, and tumor lysis syndrome 1 percent (1 percent Grade III). No deaths were attributed to tisagenlecleucel including no fatal cases of CRS or neurologic events. No cerebral edema was observed.[52] Study 2 safety results were consistent to those of Study 1.[53]

After reviewing the studies provided by the applicant, we are concerned that the applicant included patients who were diagnosed with TFL and PMBCL in the SCHOLAR–1 data results for their comparison analysis, possibly skewing results. Furthermore, the discontinue rate of the JULIET trial was high. Of 147 patients enrolled for infusion involving KYMRIAH™, 43 discontinued prior to infusion (9 discontinued due to inability to manufacture, and 34 discontinued due to patient-related issues). Finally, the rate of patients who experienced a diagnosis of CRS was high, 58 percent.[54]

The applicant for YESCARTA™ stated that YESCARTA™ represents a substantial clinical improvement over existing technologies when used in the treatment of patients with aggressive B-cell NHL. The applicant asserted that YESCARTA™ can benefit the patient population with the highest unmet need, patients with R/R disease after failure of first-line or second-line therapy, and patients who have failed or who are ineligible for ASCT. These patients, otherwise, have adverse outcomes as demonstrated by historical control data.

Regarding clinical data for YESCARTA™, the applicant stated that historical control data was the only ethical and feasible comparison information for these patients with chemorefractory, aggressive NHL who have no other available treatment options and who are expected to have a very short lifespan without therapy. According to the applicant, based on meta-analysis of outcomes in patients with chemorefractory DLBCL, there are no curative options for patients with aggressive B-cell NHL, regardless of refractory subgroup, line of therapy, and disease stage with their median OS being 6.6 months.[55]

In the applicant's FY 2018 new technology add-on payment application for the KTE–C19 technology, which was discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19889), the applicant cited ongoing clinical trials. The applicant provided updated data related to these ongoing clinical trials as part of its FY 2019 application for YESCARTA™.[56] [57] [58] The updated analysis of the pivotal Study 1 (ZUMA–1, KTE–C19–101), Phase I and II occurred when patients had been followed for 12 months after infusion of YESCARTA™. Study 1 is a Phase I–II multi-center, open-label study evaluating the safety and efficacy of the use of YESCARTA™ in patients with aggressive refractory NHL. The trial consists of two distinct phases designed as Phase I (n=7) and Phase II (n=101). Phase II is a multi-cohort open-label study evaluating the efficacy of YESCARTA™.[59] The applicant noted that, as of the analysis cutoff date for the interim analysis, the results of Study 1 demonstrated rapid and substantial improvement in objective, or ORR. After 6 and 12 months, the ORR was 82 and 83 percent, respectively. Consistent response rates were observed in both Study 1, Cohort 1 (DLBCL; n=77) and Cohort 2 (PMBCL or TFL; n=24) and across covariates including disease stage, age, IPI scores, CD–19 status, and refractory disease subset. In the updated analysis, results were consistent across age groups. In this analysis, 39 percent of patients younger than 65 years old were in ongoing response, and 50 percent of patients at least 65 years old or older were in ongoing response. Similarly, the survival rate at 12 months was 57 percent among patients younger than 65 years old and 71 percent among patients at least 65 years old or older versus historical control of 26 percent. The applicant further stated that evidence of substantial clinical improvement regarding the efficacy of YESCARTA™ for the treatment of patients with chemorefractory, aggressive B-cell NHL is supported by the CR of YESCARTA™ in Study 1, Phase II (54 percent) versus the historical control (7 percent).[60] [61] [62] [63]

[50] *ClinicalTrials.gov*, ''Phase IIa study of redirected autologous T-cells engineered to contain anti-CD19 attached to TCRz and 4-signaling domains in patients with chemotherapy relapsed or refractory CD19+ lymphomas.'' Available at: *https://clinicaltrials.gov/ct2/show/NCT02030834.*

[51] Schuster, S.J., Svoboda, J., Nasta, S.D., et al., ''Sustained remissions following chimeric antigen receptor modified T-cells directed against CD–19 (CTL019) in patients with relapsed or refractory CD19+ lymphomas,'' Presented at: 57th Annual Meeting of the American Society of Hematology, December 6, 2015, Orlando, FL.

[52] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[53] Ibid.

[54] Schuster, S.J., Bishop, M.R., Tam, C., et al., ''Global trial of the efficacy and safety of CTL019 in adult patients with relapsed or refractory diffuse large B-cell lymphoma: an interim analysis,'' Presented at: 22nd Congress of the European Hematology Association, June 22–25, 2017, Madrid, Spain.

[55] Seshardi, T., et al., ''Salvage therapy for relapsed/refractory diffuse large B-cell lymphoma,'' *Biol Blood Marrow Transplant,* 2008 Mar, vol. 14(3), pp. 259–67.

[56] Locke, F.L., et al., ''Ongoing complete remissions in Phase 1 of ZUMA–1: A phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[57] Locke, F.L., et al., ''Primary results from ZUMA–1: A pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[58] Locke, F.L., et al., ''Phase I results of ZUMA–1: A multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[59] Neelapu, S.S., Locke, F.L., et al., 2016, ''KTE–C19 (anti-CD19 CAR T cells) induces complete remissions in patients with refractory diffuse large B-cell lymphoma (DLBCL): Results from the pivotal Phase II ZUMA–1,'' Abstract presented at American Society of Hematology (ASH) 58th Annual Meeting, December 2016.

[60] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[61] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with

The applicant noted that CR rates were observed in both Study 1, Cohort 1. The applicant reported that, in the updated analysis, results were in ongoing response (46 percent of patients at least 65 years old or older were in ongoing response). Similarly, the survival rate at 12 months was 57 percent among patients younger than 65 years old and 71 percent among patients at least 65 years old or older.[64] [65] [66] [67] The applicant also provided the following tables to depict data to support substantial clinical improvement (we refer readers to the two tables below).

OVERALL RESPONSE RATES ACROSS ALL YESCARTA™ STUDIES VS. SCHOLAR–1

%	Study 1, Phase I n=7	Study 1, Phase II n=101	Scholar-1 n=529
Overall Response Rate (%)	71	83	26
Month 6 (%)	43	41	.....
Ongoing with >15 Months of follow-up (%)	43	42	.....
Ongoing with >18 Months of follow-up (%)	43	Follow-up ongoing	.....

RESULTS FOR YESCARTA™ STUDY 1, PHASE II: COMPLETE RESPONSE

	Study 1, Phase II n=101
Complete Response (%) (95 Percent Confidence Interval)	54 (44,64).
Duration of Response, median (range in months)	not reached.
Ongoing Responses, CR (%); Median 8.7 months follow-up; median overall survival has not been reached	39.
Ongoing Responses, CR (%); Median 15.3 months follow-up; median overall survival has not been reached	40.

According to the applicant, the 6-month and 12-month survival rates (95 percent CI) for patients enrolled in the SCHOLAR–1 study were 53 percent (49 percent, 57 percent) and 28 percent (25 percent, 32 percent).[68] In contrast, the 6-month and 12–month survival rates (95 percent CI) in the Study 1 updated analysis were 79 percent (70 percent, 86 percent) and 60 percent (50 percent, 69 percent).[69] [70] [71]

The applicant also cited safety results from the pivotal Study 1, Phase II. According to the applicant, the clinical trial protocol stipulated that patients were infused with YESCARTA™ in the hospital inpatient setting and were monitored in the inpatient setting for at least 7 days for early identification and treatment involving YESCARTA™-related toxicities, which primarily included CRS diagnoses and neurotoxicities. The applicant noted that the interim analysis showed the length of stay following infusion of YESCARTA™ was a median of 15 days. Ninety-three percent of patients experienced CRS diagnoses, 13 percent of whom experienced Grade III or higher (severe, life threatening or fatal) CRS diagnoses. The median time to onset of CRS diagnosis was 2 days (range 1 to 12 days) and the median time to resolution was 8 days. Ninety-eight percent of patients recovered from CRS diagnosis. Neurologic events occurred in 64 percent of patients, 28 percent of whom experienced Grade III or higher (severe or life threatening) events. The median time to onset of neurologic events was 5 days (range 1 to 17 days). The median time to resolution was 17 days. Nearly all patients recovered from neurologic events. The medications most often used to treat these complications included growth factors, blood products, anti-infectives, steroids, tocilizumab, and vasopressors. Two patients died from YESCARTA™-related adverse events (hemophagocytic lymphohistiocytosis and cardiac arrest in the hospital setting as a result of CRS diagnoses). According to the applicant, there were no clinically important differences in adverse event rates across age groups (younger than 65 years old; 65 years old or older), including CRS diagnoses and neurotoxicity.[72] [73]

The applicant for YESCARTA™ provided information regarding a safety expansion cohort, Study 1 Phase II Safety Expansion Cohort 3 that was created and carried out in 2017.

refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[62] Locke, F.L., et al., ''Phase I results of ZUMA–1: A multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[63] Crump, et al., 2017, ''Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study,'' *Blood,* vol. 0, 2017, pp. blood-2017-03-769620v1.

[64] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: A phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[65] Locke, F.L., et al., ''Primary results from ZUMA–1: A pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[66] Locke, F.L., et al., ''Phase I results of ZUMA–1: A multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[67] Crump, et al., ''Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR–1 study,'' *Blood,* vol. 0, 2017, pp. blood-2017-03-769620v1.

[68] Crump, et al., ''Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study,'' *Blood,* vol. 0, 2017, pp. blood-2017-03-769620v1.

[69] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[70] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

[71] Locke, F.L., et al., ''Phase I results of ZUMA–1: a multicenter study of KTE–C19 anti-CD19 CAR T cell therapy in refractory aggressive lymphoma,'' *Mol Ther,* vol. 25, No 1, January 2017.

[72] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[73] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (axi-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

According to the applicant, this Safety Expansion Cohort investigated measures to mitigate the incidence and/or severity of anti-CD–19 CAR T therapy and evaluated an adverse event mitigation strategy by prophylactically using levetiracetam (Keppra), an anticonvulsant, and tocilizumab, an IL–6 receptor inhibitor. Of the 30 patients treated, 2 patients experienced Grade III CRS diagnoses; 1 of the 2 patients recovered. In late April 2017, the other patient also experienced multi-organ failure and a neurologic event that subsequently progressed to a fatal Grade V cerebral edema that was deemed related to YESCARTA™ treatment. This case of cerebral edema was observed in a 21 year-old male with refractory, rapidly progressive, symptomatic, stage IVB PMBCL. Analysis of the baseline serum and cerebrospinal fluid (CSF) obtained prior to any study treatment demonstrated high cytokine and chemokine levels. According to the applicant, this suggests a significant preexisting underlying inflammatory process, both systemically and within the central nervous system. Rapidly progressing disease, recent mediastinal XRT (external beam radiation therapy) and/or CMV (cytomegalovirus) reactivation may have contributed to the pre-existing state. There were no prior cases of cerebral edema in the 200 patients who have been treated with YESCARTA™ in the ZUMA clinical development program. The single patient event from the Study 1 Phase II Safety Expansion Cohort 3 was the first Grade V cerebral edema event.[74] [75]

After reviewing the information submitted by the applicant as part of its FY 2019 new technology add-on payment application for YESCARTA™, we are concerned that it does not appear to include patient mortality data that was included as part of the applicant's FY2018 new technology add-on payment application for the KTE–C19 technology. In that application, as discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19890), the applicant provided that by an earlier cutoff date for the interim analysis of Study 1, among all KTE–C19 treated patients, 12 patients in Study 1, Phase II, including 10 from Cohort 1, and 2 from Cohort 2, died. Eight of these deaths were due to disease progression. One patient had disease progression after receiving KTE–C19 treatment and subsequently had ASCT. After ASCT, the patient died due to sepsis. Two patients (3 percent) died due to KTE–C19-related adverse events (Grade V hemophagocytic lymphohistiocytosis event and Grade V anoxic brain injury), and one died due to an adverse event deemed unrelated to treatment involving KTE–C19 (Grade V pulmonary embolism), without disease progression. We believe it would be relevant to include this information because it is related to the same treatment that is the subject of the applicant's FY 2019 new technology add-on payment application.

We also are concerned that there are few published results showing any survival benefits from the use of this treatment. In addition, we are concerned with the limited number of patients (n=108) that were studied after infusion involving YESCARTA™ T-cell immunotherapy. Finally, we are concerned about the data related to the percentage of patients who experience complications or toxicities related to YESCARTA™ treatment. According to the applicant, of the patients who participated in YESCARTA™ clinical trials, 93 percent developed CRS diagnoses and 64 percent experienced neurological adverse events.

We are inviting public comments on whether KYMRIAH™ and YESCARTA™ meet the substantial clinical improvement criterion.

Finally, we believe that in the context of these pending new technology add-on payment applications, there may also be merit in the suggestions from the public to create a new MS–DRG for the assignment of procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients who receive treatment involving CAR T-cell therapy as an alternative to our proposed MS–DRG assignment to MS–DRG 016 for FY 2019, or the suggestions to allow hospitals to utilize a CCR specific to procedures involving the utilization of KYMRIAH™ and YESCARTA™ CAR T-cell therapy drugs for FY 2019 as part of the determination of the cost of a case for purposes of calculating outlier payments for individual FY 2019 cases, new technology add-on payments, if approved, for individual FY 2019 cases, and payments to IPPS-excluded cancer hospitals beginning in FY 2019. If as discussed in section II.F.2.d. of the preamble of this proposed rule 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. With respect to an alternative considered for the use of a CCR specific to procedures involving the utilization of KYMRIAH™ and YESCARTA™ CAR T-cell therapy drugs for FY 2019 as part of the determination of the cost of a case for purposes of calculating outlier payments for individual FY 2019 cases, new technology add-on payments, if approved, for individual FY 2019 cases, and payments to IPPS-excluded cancer hospitals beginning in FY 2019, we refer readers to the discussion in section II.A.4.g.2. of the Addendum to this proposed rule.

We are inviting public comments regarding the most appropriate mechanism to provide payment to hospitals for new technologies such as CAR T-cell therapy drugs, including through the use of new technology add-on payments.

We also are inviting public comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices, which is a high priority for this Administration. In addition, we are considering alternative approaches and authorities to encourage value-based care and lower drug prices. We solicit comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches.

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 application of KYMRIAH™ for new technology add-on payments for FY 2019.

Below we summarize and respond to a written public comment we received during the open comment period regarding YESCARTA™ in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: The applicant commented that the use of YESCARTA™ as a treatment option has resulted in unprecedented and consistent treatment for patients with refractory large B-cell lymphoma who previously did not have a curative option. In addition, the applicant summarized the substantial clinical improvement differences between YESCARTA™ and the results of KYMRIAH™'s SCHOLAR–1 study. The applicant noted that, for the patients enrolled in the SCHOLAR–1 study, the median overall survival was 6 months and complete remission was

[74] Locke, F.L., et al., ''Ongoing complete remissions in Phase I of ZUMA–1: a phase I–II multicenter study evaluating the safety and efficacy of KTE–C19 (anti-CD19 CAR T cells) in patients with refractory aggressive B-cell non-Hodgkin lymphoma (NHL),'' Oral presentation (abstract 10480) presented at European Society for Medical Oncology (ESMO), October 2016.

[75] Locke, F.L., et al., ''Primary results from ZUMA–1: a pivotal trial of axicabtagene ciloretroleucel (aci-cel; KTE–C19) in patients with refractory aggressive non-Hodgkins lymphoma (NHL),'' Oral presentation, American Association of Cancer Research (AACR).

7 percent. Conversely, the applicant conveyed that, for the patients enrolled in YESCARTA™'s Study 1, at median 15.4 months follow-up, responses were ongoing in 42 percent of the patients and 40 percent of the patients were in complete remission.

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 YESCARTA™ for FY 2019.

We note that the applicant also provided comments that were unrelated to the substantial clinical improvement criterion. As stated earlier, the purpose of the new technology town hall meeting is specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2019. Therefore, we are not summarizing these additional comments in this proposed rule. However, the applicant may resubmit its comments in response to proposals presented in this proposed rule.

b. VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection)

Jazz Pharmaceuticals, Inc. submitted an application for new technology add-on payments for the VYXEOS™ technology for FY 2019. (We note that Celator Pharmaceuticals, Inc. submitted an application for new technology add-on payments for VYXEOS™ for FY 2018. However, Celator Pharmaceuticals did not receive FDA approval by the July 1, 2017 deadline for applications for FY 2018.) 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).

AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (immature bone marrow white blood cells), red blood cells, and platelets. If left untreated, AML progresses rapidly. Normally, the bone marrow makes blood stem cells that develop into mature blood cells over time. Stem cells have the potential to develop into many different cell types in the body. Stem cells can act as an internal repair system, dividing, essentially without limit, to replenish other cells. When a stem cell divides, each new cell has the potential to either remain a stem cell or become a specialized cell, such as a muscle cell, a red blood cell, or a brain cell, among others. A blood stem cell may become a myeloid stem cell or a lymphoid stem cell. Lymphoid stem cells become white blood cells. A myeloid stem cell becomes one of three types of mature blood cells: (1) Red blood cells that carry oxygen and other substances to body tissues; (2) white blood cells that fight infection; or (3) platelets that form blood clots and help to control bleeding. In patients diagnosed with AML, the myeloid stem cells usually become a type of myeloblast. The myeloblasts in patients diagnosed with AML are abnormal and do not become healthy white blood cells. Sometimes in patients diagnosed with AML, too many stem cells become abnormal red blood cells or platelets. These abnormal cells are called leukemia cells or blasts.

AML is defined by the World Health Organization (WHO) as greater than 20 percent blasts in the bone marrow or blood. AML can also be diagnosed if the blasts are found to have a chromosome change that occurs only in a specific type of AML diagnosis, even if the blast percentage does not reach 20 percent. Leukemia cells can build up in the bone marrow and blood, resulting in less room for healthy white blood cells, red blood cells, and platelets. When this occurs, infection, anemia, or increased risk for bleeding may result. Leukemia cells can spread outside the blood to other parts of the body, including the central nervous system (CNS), skin, and gums.

Treatment of AML diagnoses usually consists of two phases; remission induction and post-remission therapy. Phase one, remission induction, is aimed at eliminating as many myeloblasts as possible. The most common used remission induction regimens for AML diagnoses are the ''7+3'' regimens using an antineoplastic and an anthracycline. Cytarabine and daunorubicin are two commonly used drugs for ''7+3'' remission induction therapy. Cytarabine is continuously administered intravenously over the course of 7 days, while daunorubicin is intermittently administered intravenously for the first 3 days. The ''7+3'' regimen typically achieves a 70 to 80 percent complete remission (CR) rate in most patients under 60 years of age.

High rates of CR are not generally seen in older patients for a number of reasons, such as different leukemia biology, much higher incidence of adverse cytogenetic abnormalities, higher rate of multidrug resistant leukemic cells, and comparatively lower patient performance status (the standard criteria for measuring how the disease impacts a patient's daily living abilities). Intensive induction therapy has worse outcomes in this patient population.[76] The applicant asserted that many older adults diagnosed with AML have a poor performance status [77] at presentation and multiple medical comorbidities that make the use of intensive induction therapy quite difficult or contraindicated altogether. Moreover, the CR rates of poor-risk patients diagnosed with AML are substantially lower in patients over 60 years of age; owing to a higher proportion of secondary AML, disease developing in the setting of a prior myeloid disorder, or prior cytotoxic chemotherapy. Therefore, less than half of older adults diagnosed with AML achieve CR with combination induction regimens.[78]

According to the applicant, the combination of cytarabine and an anthracycline, either as ''7+3'' regimens or as part of a different regimen incorporating other cytotoxic agents, may be used as so-called ''salvage'' induction therapy in the treatment of adults diagnosed with AML who experience relapse in an attempt to achieve CR. According to the applicant, while CR rates of success vary widely depending on underlying disease biology and host factors, there is a lower success rate overall in achievement of CR with ''7+3'' regimens compared to VYXEOS™ therapy. According to the applicant, ''7+3'' regimens produce a CR rate of approximately 50 percent in younger adult patients who have relapsed, but were in CR for at least 1 year.[79]

VYXEOS™ is a nano-scale liposomal formulation containing a fixed combination of cytarabine and daunorubicin in a 5:1 molar ratio. This formulation was developed by the applicant using a proprietary system known as CombiPlex. According to the applicant, CombiPlex addresses several fundamental shortcomings of conventional combination regimens, specifically the conventional ''7+3'' free drug dosing, as well as the challenges inherent in combination drug development, by identifying the most effective synergistic molar ratio of the

[76] Juliusson, G., Lazarevic, V., Horstedt, A.S., Hagberg, O., Hoglund, M., ''Acute myeloid leukemia in the real world: why population-based registries are needed'', *Blood,* 2012 Apr 26; vol. 119(17), pp. 3890–9.

[77] Stone, R.M., et al., (2004), ''Acute myeloid leukemia. Hematology'', Am Soc Hematol Educ Program, 2004, pp. 98–117.

[78] Appelbaum, F.R., Gundacker, H., Head, D.R., ''Age and acute myeloid leukemia'', *Blood* 2006, vol. 107, pp. 3481–3485.

[79] Kantarjian, H., Rayandi, F., O'Brien, S., et al., ''Intensive chemotherapy does not benefit most older patients (age 70 years and older) with acute myeloid leukemia,'' *Blood,* 2010, vol. 116(22), pp. 4422.

drugs being combined *in vitro,* and fixing this ratio in a nano-scale drug delivery complex to maintain the optimized combination after administration and ensuring exposure of this ratio to the tumor.

Cytarabine and daunorubicin are co-encapsulated inside the VYXEOS™ liposome at a fixed ratiometrically, optimized 5:1 cytarabine:daunorubicin molar ratio. According to the applicant, encapsulation maintains the synergistic ratios, reduces degradation, and minimizes the impact of drug transporters and the effect of known resistant mechanisms. The applicant stated that the 5:1 molar ratio has been shown, *in vitro,* to maximize synergistic antitumor activity across multiple leukemic and solid tumor cell lines, including AML, and in animal model studies to be optimally efficacious compared to other cytarabine:daunorubicin ratios. In addition, the applicant stated that in clinical studies, the use of VYXEOS™ has demonstrated consistently more efficacious results than the conventional ''7+3'' free drug dosing. VYXEOS™ is intended for intravenous administration after reconstitution with 19 mL sterile water for injection. VYXEOS™ is administered as a 90-minute intravenous infusion on days 1, 3, and 5 (induction therapy), as compared to the ''7+3'' free drug dosing, which consists of two individual drugs administered on different days, including 7 days of continuous infusion.

With regard to the newness criterion, 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 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 VYXEOS™ does not use the same or similar mechanism of action to achieve a therapeutic outcome as any other drug assigned to the same or a different MS–DRG. The applicant stated that no other AML treatment is designed, nor is able, to deliver a fixed, ratiometrically optimized and synergistic drug:drug ratio of 5:1 cytarabine to daunorubicin, and selectively target and accumulate at the site of malignancy, while minimizing unwanted exposure, which the applicant based on the data results of preclinical and clinical studies of the use of VYXEOS™. The applicant indicated that VYXEOS™ is a nano-scale liposomal formulation of a fixed combination of cytarabine and daunorubicin. Further, the applicant stated that the rationale for the development of VYXEOS™ is based on prolonged delivery of synergistic drug ratios utilizing the applicant's proprietary, ratiometric CombiPlex technology. According to the applicant, conventional ''7+3'' free drug dosing has no delivery complex, and these individual drugs are administered without regard to their ratio dependent interaction. According to the applicant, enzymatic inactivation and imbalanced drug efflux and transporter expression reduce drug levels in the cell. Further, decreased cytotoxicity leads to cell survival, emergence of drug resistant cells, and decreased overall survival.

The applicant provided the results of clinical studies to demonstrate that the CombiPlex technology and the ratiometric dosing of VYXEOS™ represent a shift in anticancer agent delivery, whereby the fixed, optimized dosing provides less drug to achieve improved efficacy, while maintaining a favorable risk-benefit profile. The results of this ratiometric dosing approach are in contrast to the typical combination chemotherapy development that establishes the recommended dose of one agent and then adds subsequent drugs to the combination at increasing concentrations until the aggregate effects of toxicity are considered to be limiting (the ''7+3'' drug regimen). According to the applicant, this current approach to combination chemotherapy development assumes that maximum therapeutic activity will be achieved with maximum dose intensity for all drugs in the combination, and ignores the possibility that more subtle concentration-dependent drug interactions could result in frankly synergistic outcomes.

The applicant maintained that, while VYXEOS™ contains no novel active agents, its innovative drug delivery mechanism appears to be a superior way to deliver the two active compounds in an effort to optimize their efficacy in killing leukemic blasts. However, we are concerned it is possible that VYXEOS™ may use a similar mechanism of action compared to currently available treatment options because both the current treatment regimen and VYXEOS™ are used in the treatment of AML by intravenous administration of cytarabine and daunorubicin. We are concerned that the mechanism of action of the ratiometrically fixed liposomal formulation of VYXEOS™ is the same or similar to that of the current intravenous administration of cytarabine and daunorubicin.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we believe that potential cases representing patients who may be eligible for treatment involving VYXEOS™ would be assigned to the same MS-DRGs as cases representing patients who receive treatment for diagnoses of AML.

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 asserted that VYXEOS™ is indicated for use in the treatment of patients who have been diagnosed with high-risk AML. The applicant also asserted that VYXEOS™ is the first and only approved fixed combination of cytarabine and daunorubicin and is designed to uniquely control the exposure using a nano-scale drug delivery vehicle leading to statistically significant improvements in survival in patients who have been diagnosed with high-risk AML compared to the conventional ''7+3'' free drug dosing. We believe that VYXEOS™ involves the treatment of the same patient population as other AML treatment therapies.

The following unique ICD–10–PCS codes were created to describe the administration of VYXEOS™: XW033B3 (Introduction of cytarabine and caunorubicin liposome antineoplastic into peripheral vein, percutaneous approach, new technology group 3) and XW043B3 (Introduction of cytarabine and daunorubicin liposome antineoplastic into central vein, percutaneous approach, new technology group 3).

We are inviting public comments on whether VYXEOS™ is substantially similar to existing technology, including whether the mechanism of action of VYXEOS™ differs from the mechanism of action of the currently available treatment regimen. We also are inviting public comments on whether VYXEOS™ meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant used the FY 2016 MedPAR Hospital Limited Data Set (LDS) to assess the MS–DRGs to which cases representing potential patient hospitalizations that may be eligible for treatment involving VYXEOS™ would most likely be assigned. These potential cases representing patients who may be VYXEOS™ candidates were identified if they: (1) Were diagnosed with acute myeloid leukemia (AML); and (2) received chemotherapy during their

hospital stay. The cohort was further limited by excluding patients who had received bone marrow transplants. The cohort used in the analysis is referred to in this discussion as the primary cohort.

According to the applicant, the primary cohort of cases spans 131 unique MS–DRGs, 16 of which contained more than 10 cases. The most common MS–DRGs are MS–DRG 837, 834, 838, and 839. These 4 MS–DRGs account for 4,457 (81 percent) of the 5,483 potential cases in the cohort.

The case-weighted unstandardized charge per case is approximately $185,844. The applicant then removed charges related to other chemotherapy agents because VYXEOS™ would replace the need for the use of current chemotherapy agents. The applicant explained that charges for chemotherapy drugs are grouped with charges for oncology, diagnostic radiology, therapeutic radiology, nuclear medicine, CT scans, and other imaging services in the ''Radiology Charge Amount.'' According to the applicant, removing 100 percent of the ''Radiology Charge Amount'' would understate the cost of care for treatment involving VYXEOS™ for patients who may be eligible because treatment involving VYXEOS™ would be unlikely to replace many of the services captured in the ''Radiology Charge Amount'' category. The applicant found that chemotherapy charges represent less than 20 percent of the charges associated with revenue centers grouped into the ''Radiology Charge Amount'' and removed 20 percent of the radiology charge amount in order to capture the effect of removing chemotherapy pharmacy charges. The applicant noted that regardless of the type of induction chemotherapy, patients being treated for AML have AML-related complications, such as bleeding or infection that require supportive care drug therapy. For this reason, it is expected that eligible patients receiving treatment involving VXYEOS™ will continue to incur other pharmacy and IV therapy charges for AML-related complications.

After removing the charges for the prior technology, the applicant standardized the charges. The applicant then applied an inflation factor of 1.09357, the value used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to update the charges from FY 2016 to FY 2018. According to the applicant, for the primary new technology add-on payment cohort, the cost criterion was met without consideration of VYXEOS™ charges. The average case-weighted standardized charge was $170,458, which exceeds the average case-weighted Table 10 MS–DRG threshold amount of $82,561 by $87,897.

The applicant provided additional analyses with the inclusion of VYXEOS™ charges under 3-vial, 4-vial, 6-vial, and 10-vial treatment scenarios. According to the applicant, the cost criterion was satisfied in each of these scenarios, with charges in excess of the average case-weighted threshold amount.

Finally, the applicant also provided the following sensitivity analyses (that did not include charges for VYXEOS™) using the methodology above:

- Sensitivity Analysis 1—limits the cohort to patients who have been diagnosed with AML without remission (C92.00 or C92.50) who received chemotherapy and did not receive bone marrow transplant.
- Sensitivity Analysis 2—the modified cohort was limited to patients who have been diagnosed with relapsed AML who received chemotherapy and did not receive bone marrow transplant.
- Sensitivity Analysis 3—the modified cohort was limited to patients who have been diagnosed with AML and who did not receive bone marrow transplant.
- Sensitivity Analysis 4—the primary cohort was maintained, but 100 percent of the charges for revenue centers grouped into the ''Pharmacy Charge Amount'' were excluded.
- Sensitivity Analysis 5—identifies patients who have been diagnosed with AML in remission.

The applicant noted that, in all of the sensitivity analysis scenarios, the average case-weighted standardized charge per case exceeded the average case-weighted Table 10 MS–DRG threshold amount. Based on all of the analyses above, the applicant maintained that VYXEOS™ meets the cost criterion. We are inviting public comments on whether VYXEOS™ meets the cost criterion.

With regard to substantial clinical improvement, according to the applicant, clinical data results have shown that the use of VYXEOS™ represents a substantial clinical improvement for the treatment of AML in newly diagnosed high-risk, older (60 years of age and older) patients, marked by statistically significant improvements in overall survival, event free survival and response rates, and in relapsed patients age 18 to 65 years of age, where a statistically significant improvement in overall survival has been documented for the poor-risk subset of patients as defined by the European Prognostic Index. In both groups of patients, the applicant stated that there was significant improvement in survival for the high-risk patient group. The applicant provided the following specific clinical data results.

- The applicant stated that clinical data results show that treatment with VYXEOS™ for older patients (60 years of age and older) who have been diagnosed with untreated, high-risk AML will result in superior survival rates, as compared to patients treated with conventional ''7+3'' free drug dosing. The applicant provided a summary of the pivotal Phase III Study 301 in which 309 patients were enrolled, with 153 patients randomized to the VYXEOS™ treatment arm and 156 to the ''7+3'' free drug dosing treatment arm. Among patients who were 60 to 69 years old, there were 96 patients in the VYXEOS™ treatment arm and 102 in the ''7+3'' free drug dosing treatment arm. For patients who were 70 to 75 years old, there were 57 and 54 patients in each treatment arm, respectively. The applicant noted that the data results from the Phase III Study 301 demonstrated that first-line treatment of patients diagnosed with high-risk AML in the VYXEOS™ treatment arm resulted in substantially greater median overall survival of 9.56 months versus 5.95 months in the ''7+3'' free drug dosing treatment arm (hazard ratio of 0.69; p =0.005).
- The applicant further asserted that high-risk, older patients (60 years old and older) previously untreated for diagnoses of AML will have a lower risk of early death when treated with VYXEOS™ than those treated with the conventional ''7+3'' free drug dosing. The applicant cited Medeiros, et al.,[80] which reported a large observational study of Medicare beneficiaries and noted the following: The data result of the study showed that 50 to 60 percent of elderly patients diagnosed with AML remain untreated following diagnosis; treated patients were more likely younger, male, and married, and less likely to have secondary diagnoses of AML, poor performance indicators, and poor comorbidity scores compared to untreated patients; and in multivariate survival analyses, treated patients exhibited a significant 33 percent lower risk of death compared to untreated patients.

Based on data from the Phase III Study 301,[81] the applicant cited the

[80] Medeiros, B., et al., ''Big data analysis of treatment patterns and outcomes among elderly acute myeloid leukemia patients in the United States'', *Ann Hematol,* 2015, vol. 94(7), pp. 1127–1138.

[81] Lancet, J., et al., ''Final results of a Phase III randomized trial of VYXEOS (CPX–351) versus 7+3 in older patients with newly diagnosed, high-risk

Continued

following results: The rate of 60-day mortality was less in the VYXEOS™ treatment arm (13.7 percent) versus the ''7+3'' free drug dosing treatment arm (21.2 percent); the reduction in early mortality was due to fewer deaths from refractory AML (3.3 percent versus 11.3 percent), with very similar rates of 60-day mortality due to adverse events (10.4 percent versus 9.9 percent); there were fewer deaths in the VYXEOS™ treatment arm versus the ''7+3'' free drug dosing treatment arm during the treatment phase (7.8 percent versus 11.3 percent); and there were fewer deaths in the VYXEOS™ treatment arm during the follow-up phase than in the ''7+3'' free drug dosing treatment arm (59.5 percent versus 71.5 percent).

• The applicant asserted that high-risk, older patients (60 years old and older) previously untreated for a diagnosis of AML exhibited statistically significant improvements in response rates after treatment with VYXEOS™ versus treatment with the conventional ''7+3'' free drug chemotherapy dosing, suggesting that the use of VYXEOS™ is a superior pre-transplant induction treatment versus ''7+3'' free drug dosing. Restoration of normal hematopoiesis is the ultimate goal of any therapy for AML diagnoses. The first phase of treatment consists of induction chemotherapy, in which the goal is to ''empty'' the bone marrow of all hematopoietic elements (both benign and malignant), and to allow repopulation of the marrow with normal cells, thereby yielding remission. According to the applicant, post-induction response rates were significantly higher following the use of VYXEOS™, which elicited a 47.7 percent total response rate and a 37.3 percent rate for CR, whereas the total response and CR rates for the ''7+3'' free drug dosing arm were 33.3 percent and 25.6 percent, respectively. The CR + CRi rates for patients who were 60 to 69 years of age were 50.0 percent in the VYXEOS™ treatment arm and 36.3 percent in the ''7+3'' free drug dosing treatment arm, with an odds ratio of 1.76 (95 percent CI, 1.00–3.10). For patients who were 70 to 75 years old, the rates of CR + CRi were 43.9 percent in the VYXEOS™ treatment arm and 27.8 percent in the ''7+3'' free drug dosing treatment arm.

• The applicant asserted that VYXEOS™ treatment will enable high-risk, older patients (60 years old and older) to bridge to allogeneic transplant, and VYXEOS™ treated responding patients will have markedly better outcomes following transplant. The applicant stated that diagnoses of secondary AML are considered incurable with standard chemotherapy approaches and, as with other high-risk hematological malignancies, transplantation is a useful treatment alternative. The applicant further stated that autologous HSCT has limited effectiveness and at this time, only allogeneic HSCT with full intensity conditioning has been reported to produce long-term remissions. However, the applicant stated that the clinical study by Medeiros, et al. reported that, while the use of allogeneic HSCT is considered a potential cure for AML, its use is limited in older patients because of significant baseline comorbidities and increased transplant-related morbidity and mortality. Patients in either treatment arm of the Phase III Study 301 responding to induction with a CR or CR+CRi (n=125) were considered for allogeneic hematopoietic cell transplant (HCT) when possible. In total, 91 patients were transplanted: 52 (34 percent) from the VYXEOS™ treatment arm and 39 (25 percent) from the ''7+3'' free drug dosing treatment arm. Patient and AML characteristics were similar according to randomized arm, including percentage of patients in each treatment arm that underwent transplant in CR+CRi status. However, the applicant noted that the VYXEOS™ treatment arm contained a higher percentage of older patients (70 years old or older) who were transplanted (VYXEOS™, 31 percent; ''7+3'' free drug dosing, 15 percent).[82]

According to the applicant, patient outcome following transplant strongly favored patients in the VYXEOS™ treatment arm. The Kaplan-Meier analysis of the 91 transplanted patients landmarked at the time of HCT showed that patients in the VYXEOS™ treatment arm had markedly better overall survival (hazard ratio 0.46; p=0.0046). The time-dependent Adjustment Model (Cox proportional hazard ratio) was used to evaluate the contribution of VYXEOS™ treatment to overall survival rate after adjustment for transplant and showed that VYXEOS™ treatment remained a significant contributor, even after adjusting for transplant. The time-dependent Cox hazard ratio for overall survival rates in the VYXEOS™ treatment arm versus the ''7+3'' free drug dosing treatment arm was 0.51 (95 percent CI, 0.35–0.75; p=.0007).

• The applicant asserted that VYXEOS™ treatment of previously untreated older patients (60 years old and older) diagnosed with high-risk AML increases the response rate and improves survival compared to conventional ''7+3'' free drug dosing treatment in patients diagnosed with FLT3 mutation. The applicant noted the following: Approximately 20 to 30 percent of AML patients harbor some form of FLT3 mutation, AML patients with a FLT3 mutation have a higher relapse rate and poorer prognosis than the overall population diagnosed with AML, and the most common type of mutation is internal tandem duplication (ITD) mutation localized to a membrane region of the receptor.

The applicant cited Gordon, et al., 2016,[83] which reported on the significant anti-leukemic activity of VYXEOS™ treatment in AML blasts exhibiting high-risk characteristics, including FLT3–ITD, that are typically associated with poor outcomes when treated with conventional ''7+3'' free drug dosing treatment. To determine whether the improved complete remission and overall survival rates of treatment using VYXEOS™ as compared to conventional ''7+3'' free drug dosing treatment are attributable to liposome-mediated altered drug PK or direct cellular interactions with specific AML blast samples, the authors evaluated cytotoxicity in 53 AML patient specimens. Cytotoxicity results were correlated with patient characteristics, as well as VYXEOS™ treatment cellular uptake and molecular phenotype status including FLT3–ITD, which is a predictor of poor patient outcomes to conventional ''7+3'' free drug dosing treatment. The applicant stated that a notable result from this research was the observation that AML blasts exhibiting the FLT3–ITD phenotype exhibited some of the lowest IC_{50} (the 50 percent inhibitory concentration) values and, as a group, were five-fold more sensitive to the VYXEOS™ treatment than those with wild type FLT3. In addition, there was evidence that increased sensitivity to VYXEOS™ treatment was associated with increased uptake of the drug-laden liposomes by the patient-derived AML blasts. The applicant noted that Gordon, et al. 2016, concluded taken together, the data are consistent with clinical observations where VYXEOS™ treatment retains significant anti-

(secondary) AML''. Abstract and oral presentation at American Society of Clinical Oncology (ASCO), June 2016.

[82] Stone Hematology 2004; Gordon AACR 2016; NCI. Available at: *www.cancer.gov.*

[83] Gordon, M., Tardi, P., Lawrence, M.D., et al., ''CPX–351 cytotoxicity against fresh AML blasts increased for FLT3–ITD+ cells and correlates with drug uptake and clinical outcomes,'' Abstract 287 and poster presented at AACR (American Association for Cancer Research), April 2016.

leukemic activity in AML patients exhibiting high-risk characteristics. The applicant also noted that a subanalysis of Phase III Study 301 identified 22 patients who had been diagnosed with FLT3 mutation in the VYXEOS™ treatment arm and 20 in the ''7+3'' free drug dosing treatment arm, which resulted in the following response rates of FLT3 mutated patients, which were higher with VYXEOS™ treatments (15 of 22, 68.2 percent) versus ''7+3'' free drug dosing treatments (5 of 20, 25.0 percent); and the Kaplan-Meier analysis of the 42 FLT3 mutated patients showed that patients in the VYXEOS™ treatment arm had a trend towards better overall survival rates (hazard ratio 0.57; *p*=0.093).

• The applicant asserted that younger patients (18 to 65 years old) with poor risk first relapse AML have shown higher response rates with VYXEOS™ treatment versus conventional ''salvage'' chemotherapy. Overall, the applicant stated that the use of VYXEOS™ had an acceptable safety profile in this patient population based on 60-day mortality data. Study 205 [84] was a randomized study comparing VYXEOS™ treatment against the investigator's choice of first ''salvage'' chemotherapy in patients who had been diagnosed with relapsed AML after a first remission lasting greater than 1 month (VYXEOS™ treatment arm, n=81 and ''7+3'' free drug dosing treatment arm, n=44; 18 to 65 years old). Investigator's choice was almost always based on cytarabine + anthracycline, usually with the addition of one or two new agents. According to the applicant, treatment involving VYXEOS™ demonstrated a higher rate of morphological leukemia clearance among all patients, 43.2 percent versus 40.0 percent, and the advantage was most apparent in poor-risk patients, 78.7 percent versus 44.4 percent, as defined by the European Prognostic Index (EPI). In the subset analysis of this EPI poor-risk patient subset, the applicant stated there was a significant improvement in survival rate (6.6 versus 4.2 months median, hazard ratio=0.55, p=0.02) and improved response rate (39.3 percent versus 27 percent). The applicant also noted the following: the safety profile for the use of VYXEOS™ was qualitatively similar to that of control ''salvage'' therapy, with nearly identical 60-day mortality rates (14.8 percent versus 15.9 percent); among VYXEOS™ treated patients, those with no history of prior HSCT (n=59) had higher response rates (54.2 percent versus 37.8 percent) and lower 60-day mortality (10.2 percent versus 16.2 percent); overall, the use of VYXEOS™ had acceptable safety based on 60-day mortality data, with somewhat higher frequency of neutropenia and thrombocytopenia-related grade III–IV adverse events. Even though these patients are younger (18 to 65 years old) than the population studied in Phase III Study 301 (60 years old and older), Study 205 patients were at a later stage of the disease and almost all had responded to first-line therapy (cytarabine + anthracycline) and had relapsed. The applicant also cited Cortes, et al. 2015,[85] which reported that patients who have been diagnosed with first relapse AML have limited likelihood of response and short expected survival following ''salvage'' treatment with the results from literature showing that:

• Mitoxantrone, etoposide, and cytarabine induced response in 23 percent of patients, with median overall survival of only 2 months.

• Modulation of deoxycitidine kinase by fludarabine led to the combination of fludarabine and cytarabine, resulting in a 36 percent CR rate with median remission duration of 39 weeks.

• First salvage gemtuzumab ozogamicin induced CR+CRp (or CR+CRi) response in 30 percent of patients with CD33+ AML and, for patients with short first CR durations, appeared to be superior to cytarabine-based therapy.

The applicant noted that Study 205 results showed the use of VYXEOS™ retained greater anti-leukemic efficacy in patients who have been diagnosed with poor-risk first relapse AML, and produced higher morphological leukemia clearance rates (78.7 percent) compared to conventional ''salvage'' therapy (44 percent). The applicant further noted that, overall, the use of VYXEOS™ had acceptable safety profile in this patient population based on 60-day mortality data.

Based on all of the data presented above, the applicant concluded that VYXEOS™ represents a substantial clinical improvement over existing technologies. However, we are concerned that, although there was an improvement in a number of outcomes in Phase III Study 301, specifically overall survival rate, lower risk of early death, improved response rates, better outcomes following transplant, increased response rate and overall survival in patients diagnosed with FLT3 mutation, and higher response rates versus conventional ''salvage'' chemotherapy in younger patients diagnosed with poor-risk first relapse, the improved outcomes may not be statistically significant. Furthermore, we are concerned that the overall improvement in survival from 5.95 months to 9.56 months may not represent a substantial clinical improvement. In addition, the rate of adverse events in both treatment arms of Study 205, given the theoretical benefit of reduced toxicity with the liposomal formulation, was similar for both the VYXEOS™ and ''7+3'' free drug treatment groups. Therefore, we also are concerned that there is a similar rate of adverse events, such as febrile neutropenia (68 percent versus 71 percent), pneumonia (20 percent versus 15 percent), and hypoxia (13 percent versus 15 percent), with the use of VYXEOS™ as compared with the conventional ''7+3'' free drug regimen.

We are inviting public comments on whether VYXEOS™ meets the substantial clinical improvement criterion.

Below we summarize and respond to a written public comment we received regarding the VYXEOS™ during the open comment period in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: The applicant provided a written comment to provide notification of the addition of VYXEOS™ to the Category 1 Clinical Practice Guidelines in Oncology recommendation by the National Comprehensive Cancer Network. The applicant reported that the resources made available by NCCN are the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). The intent of the guidelines is to assist in the decision-making process of individuals involved in cancer treatment and care. According to the NCCN Guidelines®, Category 1 clinical practices are based upon high-level evidence, and there is uniform NCCN consensus that the intervention is appropriate. The February 7, 2018 NCCN Guidelines® for Acute Myeloid Leukemia include a recommendation for cytarabine and daunorubicin for the treatment of adult patients 60 years of age or older who have been newly diagnosed with therapy-related AML (t-AML) or AML with myelodysplasia-related changes

[84] Cortes, J., et al., ''Significance of prior HSCT on the outcome of salvage therapy with CPX–351 or conventional chemotherapy among first relapse AML patients.'' Abstract and poster presented at ASH 2011.

[85] Cortes, J., et al., (2015), ''Phase II, multicenter, randomized trial of CPX–351 (cytarabine:daunorubicin) liposome injection versus intensive salvage therapy in adults with first relapse AML,'' *Cancer,* January 2015, pp. 234–42.

(AML–RMC) to be included as a Category 1 clinical practice.[86]

Response: We appreciate the applicant's submission of additional information. We will take these comments into consideration when deciding whether to approve new technology add-on payments for VYXEOS™ for FY 2019.

c. VABOMERE™ (Meropenem-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 specific bacteria. VABOMERE™ received FDA approval on August 29, 2017.

Complicated urinary tract infections (cUTIs) are defined as chills, rigors, or fever (temperature of greater than or equal to 38.0°C); elevated white blood cell count (greater than 10,000/mm^3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; lower abdominal pain or pelvic pain. Acute pyelonephritis is defined as chills, rigors, or fever (temperature of greater than or equal to 38.0°C); elevated white blood cell count (greater than 10,000/mm^3), or left shift (greater than 15 percent immature PMNs); nausea or vomiting; dysuria, increased urinary frequency, or urinary urgency; flank pain; costo-vertebral angle tenderness on physical examination. Risk factors for infection with drug-resistant organisms do not, on their own, indicate a cUTI.[87] The increasing incidence of multidrug-resistant gram-negative bacteria, such as carbapenem-resistant Enterobacteriacea (CRE), has resulted in a critical need for new antimicrobials.

The applicant reported that it has developed a beta-lactamase combination antibiotic, VABOMERE™, to treat cUTIs, including those caused by certain carbapenem-resistant organisms. By combining the carbapenem class antibiotic meropenem with vaborbactam, VABOMERE™ protects meropenem from degradation by certain CRE strains.

The applicant stated that meropenem, a carbapenem, is a broad spectrum beta-lactam antibiotic that works by inhibiting cell wall synthesis of both gram-positive and gram-negative bacteria through binding of penicillin-binding proteins (PBP). Carbapenemase producing strains of bacteria have become more resistant to beta-lactam antibiotics, such as meropenem. However, meropenem in combination with vaborbactam, inhibits the carbapenemase activity, thereby allowing the meropenem to bind PBP and kill the bacteria.

According to the applicant, vaborbactam, a boronic acid inhibitor, is a first-in class beta-lactamase inhibitor. Vaborbactam blocks the breakdown of carbapenems, such as meropenem, by bacteria containing carbapenemases. Although vaborbactam has no antibacterial properties, it allows for the treatment of resistant infections by increasing bacterial sensitivity to meropenem. New carbapenemase producing strains of bacteria have become more resistant to beta-lactam antibiotics. However, meropenem in combination with vaborbactam, can inhibit the carbapenemase enzyme, thereby allowing the meropenem to bind PBP and kill the bacteria. The applicant stated that the vaborbactem component of VABOMERE™ helps to protect the meropenem from degradation by certain beta-lactamases, such as Klebsiella pneumonia carbapenemase (KPC). According to the applicant, VABOMERE™ is the first of a novel class of beta-lactamase inhibitors. The applicant asserted that VABOMERE™'s use of vaborbactam to restore the efficacy of meropenem is a novel approach to fighting antimicrobial resistance.

The applicant stated that VABOMERE™ is indicated for use in the treatment of adult patients 18 years old and older who have been diagnosed with cUTIs, including pyelonephritis. The recommended dosage of VABOMERE™ is 4 grams (2 grams of meropenem and 2 grams of vaborbactam) administered every 8 hours by intravenous (IV) infusion over 3 hours with an estimated glomerular filtration rate (eGFR) greater than or equal to 50 mL/min/1.73 m^2. The recommended dosage of VABOMERE™ for patients with varying degrees of renal function is included in the prescribing information. The duration of treatment is for up to 14 days.

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 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, VABOMERE™ is designed primarily for the treatment of gram-negative bacteria that are resistant to other current antibiotic therapies. The applicant stated that VABOMERE™ does not use the same or similar mechanism of action to achieve a therapeutic outcome. The applicant asserted that the vaborbactam component of VABOMERE™ is a new class of beta-lactamase inhibitor that protects meropenem from degradation by certain enzymes such as carbapenamases. The applicant indicated that the structure of vaborbactam is distinctly optimized for inhibition of serine carbapenamases and for combination with a carbapenem antibiotic. Beta-lactamase inhibitors are agents that inhibit bacterial enzymes—enzymes that destroy beta-lactam antibiotics and result in resistance to first-line as well as ''last defense'' antimicrobials used in hospitals. According to the applicant, in order for carbapenems to be effective these enzymes must be inhibited. The applicant stated that the addition of vaborbactam as a potent inhibitor against Class A and C serine beta-lactamases, particularly KPC, represents a new mechanism of action. According to the applicant, VABOMERE™'s use of vaborbactam to restore the efficacy of meropenem is a novel approach and that the FDA's approval of VABOMERE™ for the treatment of cUTIs represents a significant label expansion because mereopenem alone (without the addition of vaborbactam) is not indicated for the treatment of patients with cUTI infections. Therefore, the applicant maintained that this technology and resistance-fighting mechanism involved in the therapeutic effect achieved by VABOMERE™ is distinct from any other existing product. The applicant noted that VABOMERE™ was designated as a qualified infectious disease product (QIDP) in January 2014. This designation is given to antibacterial products that treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.

We believe that, although the molecular structure of the vaborbactam component of VABOMERE™ is unique, the bactericidal action of VABOMERE™ is the same as meropenem alone. In

[86] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), Acute Myeloid Leukemia, Version I—2018, February 7, 2018, *https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf.*

[87] Hooton, T. and Kalpana, G., 2018, ''Acute complicated urinary tract infection (including pyelonephritis) in adults,'' In A. Bloom (Ed.), UpToDate. Available at: *https://www.uptodate.com/contents/acute-complicated-urinary-tract-infection-including-pyelonephritis-in-adults.*

addition, we note that there are other similar beta-lactam/beta-lactamase inhibitor combination therapies currently available as treatment options. We are inviting public comments on whether VABOMERE™'s mechanism of action is similar to other existing technologies.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that patients who may be eligible to receive treatment involving VABOMERE™ include hospitalized patients who have been diagnosed with a cUTI. These potential cases can be identified by a variety of ICD–10–CM diagnosis codes. Therefore, potential cases representing patients who have been diagnosed with a cUTI who may be eligible for treatment involving VABOMERE™ can be mapped to multiple MS–DRGs. The following are the most commonly used MS–DRGs for patients who have been diagnosed with a cUTI: MS–DRG 690 (Kidney and Urinary Tract Infections without MCC); MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC); MS–DRG 870 (Septicemia or Sever Sepsis with Mechanical Ventilation 96+ Hours); MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ Hours with MCC); and MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ Hours without MCC). Potential cases representing patients who may be eligible for treatment with VABOMERE™ would be assigned to the same MS–DRGs as cases representing hospitalized patients who have been diagnosed with a cUTI.

With respect to the third criterion, whether the use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that the use of VABOMERE™ would treat a different patient population than existing and currently available treatment options. According to the applicant, VABOMERE™'s use of vaborbactam to restore the efficacy of meropenem is a novel approach to fighting the global and national public health crisis of antimicrobial resistance, and as such, the use of VABOMERE™ reaches different and expanded patient populations. The applicant further asserted that future patient populations are saved as well because the growth of resistant infections is slowed. The applicant believed that, because of the threat posed by gram-negative bacterial infections and the limited number of available treatments currently on the market or in development, the combination structure and development of VABOMERE™ and its potential expanded use is new. While the applicant believes that VABOMERE™ treats a different patient population, we note that VABOMERE™ is only approved for use in the treatment of adult patients who have been diagnosed with cUTIs. Therefore, it appears that VABOMERE™ treats the same population (adult patients with a cUTI) and there are already other treatment options available for diagnoses of cUTIs.

We are concerned that VABOMERE™ may be substantially similar to existing beta-lactam/beta-lactamase inhibitor combination therapies. As noted above, we are concerned that VABOMERE™ may have a similar mechanism of action, treats the same population (patients with a cUTI) and would be assigned to the same MS–DRGs (similar to existing beta-lactam/beta-lactamase inhibitor combination therapies currently available as treatment options). We are inviting public comments on whether VABOMERE™ meets the substantial similarity criteria and the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs to which cases representing potential patients who may be eligible for treatment using VABOMERE™ may map, the applicant used the Premier Research Database from 2nd Quarter 2015 to 4th Quarter 2016. According to the applicant, Premier is an electronic laboratory, pharmacy, and billing data repository that collects data from over 600 hospitals and captures nearly 20 percent of U.S. hospitalizations. The applicant's list of most common MS–DRGs is based on data regarding CRE from the Premier Research Database. According to the applicant, approximately 175 member hospitals also submit microbiology data, which allowed the applicant to identify specific pathogens such as CRE infections. Using the Premier Research Database, the applicant identified over 350 MS–DRGs containing data for 2,076 cases representing patients who had been hospitalized for CRE infections. The applicant used the top five most common MS–DRGs: MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC), MS–DRG 853 (Infectious and Parasitic Disease with O.R. Procedure with MCC), MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation >96 Hours), MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours without MCC), and MS–DRG 690 (Kidney and Urinary Tract Infections without MCC), to which 627 cases representing potential patients who may be eligible for treatment involving VABOMERE™, or approximately 30.2 percent of the total cases identified, mapped.

The applicant reported that the resulting 627 cases from the identified top 5 MS–DRGs have an average case-weighted unstandardized charge per case of $74,815. We note that, instead of using actual charges from the Premier Research Database, the applicant computed this amount based on the average case-weighted threshold amounts in Table 10 from the FY 2018 IPPS/LTCH PPS final rule. For the rest of the analysis, the applicant adjusted the average case-weighted threshold amounts (referred to above as the average case-weighted unstandardized charge per case) rather than the actual average case-weighted unstandardized charge per case from the Premier Research Database. According to the applicant, based on the Premier data, $1,999 is the mean antibiotic costs of treating patients hospitalized with CRE infections with current therapies. The applicant explained that it identified 69 different regimens that ranged from 1 to 4 drugs from a study conducted to understand the current management of patients diagnosed with CRE infections. Accordingly, the applicant estimated the removal of charges for a prior technology of $1,999. The applicant then standardized the charges. The applicant applied an inflation factor of 9.357 percent from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to inflate the charges. The applicant noted that it does not yet have sufficient charge data from hospitals and will work to supplement its application with the information once it is available. However, for purposes of calculating charges, the applicant used the average charge as the wholesale acquisition cost (WAC) price for a treatment duration of 14 days and added this amount to the average charge per case. Using this estimate, the applicant calculated the final inflated case-weighted standardized charge per case as $91,304, which exceeds the average case-weighted threshold amount of $74,815. Therefore, the applicant asserted that VABOMERE™ meets the cost criterion.

We are concerned that, as noted earlier, instead of using actual charges from the Premier Research Database, the applicant computed the average case-weighted unstandardized charge per case based on the average case-weighted threshold amounts in Table 10

from the FY 2018 IPPS/LTCH PPS final rule. Because the applicant did not demonstrate that the average case-weighted standardized charge per case for VABOMERE™ (using actual charges from the Premier Research Database) would exceed the average case-weighted threshold amounts in Table 10, we are unable to determine if the applicant meets the cost criterion. We are inviting public comments on whether VABOMERE™ meets the cost criterion, including with respect to the concern regarding the applicant's analysis.

With regard to the substantial clinical improvement criterion, the applicant believed that the results from the VABOMERE™ clinical trials clearly establish that VABOMERE™ represents a substantial clinical improvement for treatment of deadly, antibiotic resistant infections. Specifically, the applicant asserted that VABOMERE™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, and the use of VABOMERE™ significantly improves clinical outcomes for a patient population as compared to currently available treatments. The applicant provided the results of the Targeting Antibiotic Non-sensitive Gram-Negative Organisms (TANGO) I and II clinical trials to support its assertion. TANGO-I [88] was a prospective, randomized, double-blinded trial of VABOMERE™ versus piperacillin-tazobactam in patients with cUTIs and acute pyelonephritis (A/P). TANGO-I is also a noninferiority (NI) trial powered to evaluate the efficacy, safety, and tolerability of VABOMERE™ compared to piperacillin-tazobactam in the treatment of cUTI, including AP, in adult patients. There were two primary endpoints for this study, one for the FDA, which was cure or improvement and microbiologic outcome of eradication at the end-of-treatment (EOT) (day 5 to 14) in the proportion of patients in the Microbiologic Evaluable Modified Intent-to-Treat (m-MITT) population who achieved overall success (clinical cure or improvement and eradication of baseline pathogen to <104 CFU/mL), and one for the European Medicines Agency (EMA), which was the proportion of patients in the co-primary m-MITT and Microbiologic Evaluable (ME) populations who achieve a microbiologic outcome of eradication (eradication of baseline pathogen to <103 CFU/mL) at the test-of-cure (TOC) visit (day 15 to 23). The trial enrolled 550 adult patients who were randomized 1:1 to receive VABOMERE™ as a 3-hour IV infusion every 8 hours, or piperacillin 4g-tazobactam 500mg as a 30 minute IV infusion every 8 hours, for at least 5 days for the treatment of a cUTI. Therapy was set at a minimum of 5 days to fully assess the efficacy and safety of VABOMERE™. After a minimum of 5 days of IV therapy, patients could be switched to oral levofloxacin (500 mg once every 24 hours) to complete a total of 10-day treatment course (IV + oral), if they met pre-specified criteria. Treatment was allowed for up to 14 days, if clinically indicated.

Patient demographic and baseline characteristics were balanced between treatment groups in the m-MITT population.

- Approximately 93 percent of patients were Caucasian and 66 percent were females in both treatment groups.
- The mean age was 54 years old with 32 percent and 42 percent of the patients 65 years old and older in the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- Mean body mass index was approximately 26.5 kg/m^2 in both treatment groups.
- Concomitant bacteremia was identified in 12 (6 percent) and 15 (8 percent) of the patients at baseline in the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- The proportion of patients who were diagnosed with diabetes mellitus at baseline was 17 percent and 19 percent in the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- The majority of the patients (approximately 90 percent) were enrolled from Europe, and approximately 2 percent of the patients were enrolled from North America. Overall, in both treatment groups, 59 percent of the patients had pyelonephritis and 40 percent had a cUTI, with 21 percent and 19 percent of the patients having a non-removable and removable source of infection, respectively.

Mean duration of IV treatment in both treatment groups was 8 days and mean total treatment duration (IV and oral) was 10 days; patients with baseline bacteremia could receive up to 14 days of therapy (IV and oral). Approximately 10 percent of the patients in each treatment group in the m-MITT population had a levofloxacin-resistant pathogen at baseline and received levofloxacin as the oral switch therapy. According to the applicant, this protocol violation may have impacted the assessment of the outcomes at the TOC visit. These patients were not excluded from the analysis of adverse reactions (headache, phlebitis, nausea, diarrhea, and others) occurring in 1 percent or more of the patients receiving VABOMERE™, as the decision to switch to oral levofloxacin was based on post-randomization factors.

Regarding the FDA primary endpoint, the applicant stated the following:

- Overall success rate at the end of IV treatment (day 5 to 14) was 98.4 percent and 94 percent for the VABOMERE™ and piperacillin/tazobactam treatment groups, respectively.
- The TOC—7 days post IV therapy was 76.5 percent (124 of 162 patients) for the VABOMERE™ group and 73.2 percent (112 of 153 patients) for the piperacillin/tazobactam group.
- Despite being an NI trial, TANGO–I showed a statistically significant difference favoring VABOMERE™ in the primary efficacy endpoint over piperacillin/tazobactam (a commonly used agent for gram-negative infections in U.S. hospitals).
- VABOMERE™ demonstrated statistical superiority over piperacillin-tazobactam with overall success of 98.4 percent of patients treated with VABOMERE™ in the TANGO–I clinical trial compared to 94.0 percent for patients treated with piperacillin/tazobactam, with a treatment difference of 4.5 percent and 95 percent CI of (0.7 percent, 9.1 percent).
- Because the lower limit of the 95 percent CI is also greater than 0 percent, VABOMERE™ was statistically superior to piperacillin/tazobactam.
- Because non-inferiority was demonstrated, then superiority was tested. Further, the applicant asserted that a noninferiority design may have a ''superiority'' hypothesis imbedded within the study design that is appropriately tested using a non-inferiority design and statistical analysis. As such, according to the applicant, superiority trials concerning antibiotics are impractical and even unethical in many cases because one cannot randomize patients to receive inactive therapies. The applicant stated that it would be unethical to leave a patient with a severe infection without any treatment.
- The EMA endpoint of eradication rates at TOC were higher in the VABOMERE™ group compared to the piperacillin/tazobactam group in both the m-MITT (66.7 percent versus 57.7 percent) and ME (66.3 percent and 60.4 percent) populations; however, it was

[88] Vabomere Prescribing Information, Clinical Studies (August 2017), available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209776lbl.pdf.*

not a statistically significant improvement.

We note that the eradication rates of the EMA endpoint were not statistically significant. We are inviting public comments with respect to our concern as to whether the FDA endpoints demonstrating noninferiority are statistically sufficient data to support that VABOMERE™ is a substantial clinical improvement in the treatment of patients with a cUTI.

In TANGO–I the applicant offers data comparing VABOMERE™ to piperacillin–tazobactam EOT/TOC rates in the setting of cUTIs/AP, but does not offer a comparison to other antibiotic treatments of cUTIs known to be effective against gram–negative uropathogens, specifically other carbapenems.[89] We also note that the study population is largely European (98 percent), and given the variable geographic distribution of antibiotic resistance we are concerned that the use of piperacillin/tazobactam as the comparator may have skewed the eradication rates in favor of VABOMERE™, or that the favorable results would not be applicable to patients in the United States. We are inviting public comments regarding the lack of a comparison to other antibiotic treatments of cUTIs known to be effective against gram–negative uropathogens, whether the comparator the applicant used in its trial studies may have skewed the eradication rates in favor of VABOMERE™, and if the favorable results would be applicable to patients in the United States to allow for sufficient information in evaluating substantial clinical improvement.

The applicant asserted that the TANGO-II study [90] of monotherapy with VABOMERE™ compared to best available therapy (BAT) (salvage care of cocktails of toxic/poorly efficacious last resort agents) for the treatment of CRE infections showed important differences in clinical outcomes, including reduced mortality, higher clinical cure at EOT and TOC, benefit in important patient subgroups of HABP/VABP, bacteremia, renal impairment, and immunocompromised and reduced AEs, particularly lower nephrotoxicity in the study group. TANGO-II is a multi-center, randomized, Phase III, open-label trial of patients with infections due to known or suspected CRE, including cUTI, AP, HABP/VABP, bacteremia, or complicated intra-abdominal infection (cIAI). Eligible patients were randomized 2:1 to monotherapy with VABOMERE™ or BAT for 7 to 14 days. There were no consensus BAT regimes, it could include (alone or in combination) a carbapenem, aminoglycoside, polymyxin B, colistin, tigecycline or ceftazidime-avibactam.

A total of 72 patients were enrolled in the TANGO-II trial. Of these, 50 of the patients (69.4 percent) had a gram-negative baseline organism (m-MITT population), and 43 of the patients (59.7 percent) had a baseline CRE (mCRE–MITT population). Within the mCRE–MITT population, 20 of the patients had bacteremia, 15 of the patients had a cUTI/AP, 5 of the patients had HABP/VABP, and 3 of the patients had a cIAI. The most common baseline CRE pathogens were K. pneumoniae (86 percent) and Escherichia coli (7 percent). Cure rates of the mCRE–MITT population at EOT for VABOMERE™ and BAT groups were 64.3 percent and 40 percent, respectively, TOC, 7 days after EOT, were 57.1 percent and 26.7 percent, respectively, 28-day mortality was 17.9 percent (5 of 28 patients) and 33.3 percent (5 of 15 patients), respectively. The applicant asserted that with further sensitivity analysis, taking into account prior antibiotic failures among the VABOMERE™ study arm, the 28-day all-cause mortality rates were even lower among VABOMERE™ versus BAT patients (5.3 percent (1 of 19 patients) versus 33.3 percent (5 of 15 patients)). Additionally, in July 2017, randomization in the trial was stopped early following a recommendation by the TANGO-II Data Safety Monitoring Board (DSMB) based on risk-benefit considerations that randomization of additional patients to the BAT comparator arm should not continue.

According to the applicant, subgroup analyses of the TANGO-II studies include an analysis of adverse events in which VABOMERE™ compared to BAT demonstrated the following:

- VABOMERE™ was associated with less severe treatment emergent adverse events of 13.3 percent versus 28 percent.
- VABOMERE™ was less likely to be associated with a significant increase in creatinine 3 percent versus 26 percent.
- Efficacy results of the TANGO-II trial cUTI/AP subgroup demonstrated VABOMERE™ was associated with an overall success rate at EOT for the mCRE–MITT populations of 72 percent (8 of 11 patients) versus 50 percent (2 of 4 patients) and an overall success rate at TOC of 27.3 percent (3 of 7 patients) versus 50 percent (2 of 4 patients).

We note that many of the TANGO-II trial outcomes showing improvements in the use of VABOMERE™ over BAT are not statistically significant. We also note that the TANGO-II study included a small number of patients; the study population in the mCRE-MITT only included 43 patients. Additionally, the cUTI/AP subgroup analysis only included a total of 15 patients and did not show an increased overall success rate at TOC (27.3 percent versus 50 percent) over the BAT group. We are inviting public comments with respect to our concern as to whether the lack of statistically significant outcomes and the small number of study participants allows for enough information to evaluate substantial clinical improvement.

We are inviting public comments on whether the VABOMERE™ technology meets the substantial clinical improvement criterion, including with respect to the specific concerns we have raised.

Below we summarize and respond to written public comments we received regarding VABOMERE™ during the open comment period in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: The applicant submitted information regarding the comparison of VABOMERE™ to other antibiotic treatments for a cUTI known to be effective against gram-negative uropathogens. The applicant asserted that doripenem is a carbapenem antibiotic and, therefore, is subject to degradation and inactivation by carbapenemases, including the Klebsiella pneumoniae carbapenemase (KPC). The applicant stated that doripenem has been shown to have poor activity *in vitro* against CRE and VABOMERE™, in contrast, takes a novel, first in class beta-lactamase inhibitor, vaborbactam, and combines it with the carbapenem drug meropenem in a manner that—because of the unique, novel, and new properties of vaborbactam when combined with meropenem to create VABOMERE™—to effectively restore the effectiveness of meropenem (a carbapenem) in fighting against carbapenem-resistant bacteria. The applicant indicated that extensive *in vitro* studies have been conducted and show that carbapenems such as doripenem have poor activity *in vitro* against KPC-producing CRE. Because the *in vitro* data show that doripenem has poor activity against KPC-producing CRE, the applicant stated that no comparative clinical efficacy data

[89] Golan, Y., 2015, ''Empiric therapy for hospital-acquired, Gram-negative complicated intra-abdominal infection and complicated urinary tract infections: a systematic literature review of current and emerging treatment options,'' *BMC Infectious Diseases,* vol. 15, pp. 313. *http://doi.org/10.1186/s12879-015-1054-1.*

[90] Alexander, et al., ''CRE Infections: Results From a Retrospective Series and Implications for the Design of Prospective Clinical Trials,'' *Open Forum Infectious Diseases.*

between doripenem and VABOMERE™ exists.

Response: We appreciate the applicant's comments. However, we believe that because the study population for VABOMERE™ is patients with cUTIs and not UTIs with KPCs, we are concerned that the applicant does not offer comparison data to other antibiotic treatments of cUTIs known to be effective against gram-negative uropathogens. As noted, we are inviting public comments on whether the VABOMERE™ technology meets the substantial clinical improvement criterion, including with respect to the specific concerns we have raised.

d. DURAGRAFT® Vascular Conduit Solution

Somahlution, Inc. submitted an application for new technology add-on payments for DURAGRAFT® for FY 2019. DURAGRAFT® is designed to protect the endothelium of the vein graft following harvesting and prior to grafting to prevent vascular graft disease (VGD) and vein graft failure (VGF), and to reduce the clinical complications associated with graft failure. These complications include myocardial infarction and repeat revascularization. DURAGRAFT® is formulated into a solution that is used during standard graft handling, flushing, and bathing steps.

VGD is the principal cause of both early (within 30 days) and intermediate/late (months to years) VGF. The principal mediator of VGD following grafting in bypass surgeries is damage that occurs during intra-operative vascular graft harvesting and handling.[91] [92] Endothelium can be destroyed or damaged intraoperatively through the acute physical stress of harvesting, storage, and handling, and through more insidious processes such as those associated with ischemic injury, metabolic stress and oxidative damage. According to the applicant, more recently, it has been demonstrated that damage associated with graft storage solution has the highest correlation with the development of 12-month VGF.[93] [94] This is likely due not only to the active tissue damage associated with commonly used storage solutions, but also to their inability to protect against ischemic injury.[95] [96] [97] VGD encompasses the pathophysiological changes that occur in damaged vein grafts following their use in surgical grafting. These changes, apparent within minutes to hours of grafting, are manifested as endothelial dysfunction, death and/or denudation and include pro-inflammatory, pro-thrombogenic and proliferative changes within the graft. These initial responses to damage cause even more damage in a domino-like effect, thereby perpetuating the response-damage cycle that is the basis of VGD progression.

The applicant further noted that endothelial dysfunction and inflammation also result in the diminished ability of the graft to respond appropriately to new blood flow patterns and adaptive positive remodeling may be thwarted. This is because proper remodeling is dependent upon a functional endothelial response to shear stress that involves the production of remodeling factors by the endothelium including nitro vasodilators, prostaglandins, lipoxyoxygenases, hyperpolarizing factors and other growth factors. Therefore, damaged, missing and/or dysfunctional endothelial cells prevent, to varying extents, graft adaption which makes the graft susceptible to shear-mediated endothelial damage. The collective damage results in intimal hyperplasia or graft wall thickening that is the basis for atheroma development and subsequent lumen narrowing and graft failure, which is the end state of VGD. The applicant pointed to several references to highlight pathologic changes leading to VGD, occlusion and loss of vasomotor function.[98] [99] [100] [101] [102] [103] [104] [105] The applicant summarized, that when the damaged luminal surface of a vein graft is presented to the bloodstream at time of reperfusion, a domino-effect of further damage is triggered through inflammatory, thrombogenic and aberrant hyper-proliferative processes that lead to both early and late VGF. Presenting an intact functional endothelial layer at the time of grafting is, therefore, tantamount to protecting the graft and its associated endothelium from damage that occurs post-grafting, in turn conferring protection against graft failure. Given the low success rate of failed graft intervention, addressing graft endothelial protection at the time of surgery is critical.[106]

With respect to the newness criterion, DURAGRAFT® has not received FDA approval at the time of the development of this proposed rule. The applicant indicated that it anticipates FDA approval of its premarket application by the second quarter of 2018. The applicant also indicated that ICD–10–PCS code XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3) would identify procedures involving the use of the DURAGRAFT® technology.

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 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 currently no other treatment options available with the

[91] Harskamp, Ralf E., MD, Alexander, John H., MD, MHS, Schulte, Phillip J., Phd, et al., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery: follow-up from the PREVENT IV randomized clinical trial'', *Jama Surg,* 2014, vol. 149(8), pp. 798–805.

[92] Testa, L., Bedogni, F., ''Treatment of Saphenous Vein Graft Disease: 'Never Ending Story' of the Eternal Return,'' *Res Cardiovasc Med,* 2014, vol. 3(3), pp. e21092.

[93] Ibid.

[94] Ibid.

[95] Weiss, D.R., Juchem, G., Kemkes, B.M., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' Century Publishing Corporation, *International Journal of Clinical Experimental Medicine,* 2009 May 28, vol. 2(2), pp. 95–113.

[96] Wilbring, M., Tugtekin, S.M., Zatschler, B., et al., ''Even short-time storage in physiological saline solution impairs endothelial vascular function of saphenous vein grafts,'' Elsevier Science Inc., *European Journal of Cardio-Thoracic Surgery,* 2011 Oct, vol. 40(4), pp. 811–815.

[97] Thatte, H.S., Biswas, K.S., Najjar, S.F., et al., ''Multi-photon microscopic evaluation of saphenous vein endothelium and its preservation with a new solution,'' GALA, Elsevier Science Inc., *Ann Thorac Surg,* 2003 Apr, vol. 75(4), pp. 1145–1152.

[98] Verrier, E.D., Boyle, E.M., ''Endothelial cell injury in cardiovascular surgery: an overview,'' *Ann Thorac Surg,* 1997, vol. 64, pp. S2–S8.

[99] Harskamp, R.E., Lopes, R.D., Baisden, C.E., et al., ''Saphenous vein graft failure after coronary artery bypass surgery: pathophysiology, management, and future directions,'' *Ann Thorac Surg.,* 2013 May, vol. 257(5), pp. 824–33.

[100] Hess, C.N., Lopes, R.D., Gibson, C.M., et al., ''Saphenous vein graft failure after coronary artery bypass surgery: insights from PREVENT IV,'' Circulation 2014 Oct 21, vol. 130(17), pp. 1445–51.

[101] Sellke, F.W., Boyle, E.M., Verrier, E.D., ''The pathophysiology of vasomotor dysfunction,'' *Ann Thorac Surg,* 1997, vol. 64, pp. S9–S15.

[102] Motwani, J.G., Topol, E.J., ''Aortocoronary saphenous vein graft disease: pathogenesis, predisposition and prevention,'' *Circulation* 1998, vol. 97(9), pp. 916–31.

[103] Mills, N.L., Everson, C.T., ''Vein graft failure,'' *Curr Opin Cardiol,* 1995, vol. 10, pp. 562–8.

[104] Davies, M.G., Hagen, P.O., ''Pathophysiology of vein graft failure: a review,'' *Eur J Vasc Endovasc Surg,* 1995, vol. 9, pp. 7–18.

[105] Edmunds, L.H., ''Techniques of myocardial revascularization. In: Edmunds LH, ed. Cardiac surgery in the adult,'' New York: McGraw-Hill, 1997, pp. 481–534.

[106] Kim, F.Y., Marhefka, G., Ruggiero, N.J., et al., ''Saphenous vein graft disease: review of pathophysiology, prevention, and treatment,'' *Cardiol,* Rev 2013, vol. 21(2), pp. 101–9.

same mechanism of action as that of DURAGRAFT®. Moreover, the applicant conveyed there are currently no commercial solutions approved for treating arteries or veins intended for bypass surgery. The applicant explained that the DURAGRAFT® treatment has been formulated into a solution so that it can be used to treat grafts during handling, flushing, and bathing steps without changing surgical practice to perform the treatment. According to the applicant, DURAGRAFT® is specifically designed to inhibit endothelial cell damage and death, as well as prevent damage to other cells of the vascular conduit, which achieves a superior clinical outcome in coronary artery bypass grafting (CABG).

The applicant did not directly address within its application the second and third criteria; whether a product is assigned to the same or a different MS–DRG and 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. However, the applicant stated, as previously indicated, that there are currently no other treatment options available that utilize the same mechanism of action as that of the DURAGRAFT®.

Based on the applicant's statements presented above, we are concerned that the mechanism of action of the DURAGRAFT® may be the same or similar to other vein graft storage solutions. We also are concerned with the lack of information regarding how the technology meets the substantial similarity criteria. Specifically, we understand that there are other vein graft storage solutions available, such as various saline, blood, and electrolyte solutions. We believe that additional information would be helpful regarding whether the use of the technology treats the same or similar patient population or type of disease, and whether the product is assigned to the same or different MS–DRG as compared to the other storage solutions. We are inviting public comments on whether DURAGRAFT® meets the substantial similarity criteria and the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. In order to identify the range of MS–DRGs that cases representing potential patients who may be eligible for treatment using DURAGRAFT® may map to, the applicant identified all MS–DRGs for patients who underwent coronary artery bypass grafting (CABG). Specifically, the applicant searched the FY 2016 MedPAR file for claims that included IPPS patients and identified potential cases by the following ICD–10–PCS procedure codes:

ICD–10–PCS procedure code	Code title
021009W	Bypass coronary artery, one artery from aorta with autologous venous tissue, open approach.
02100AW	Bypass coronary artery, one artery from aorta with autologous arterial tissue, open approach.
021049W	Drainage of intracranial subdural space, percutaneous approach
02104AW.	Bypass cerebral ventricle to cerebral cisterns, percutaneous approach.
021109W	Bypass coronary artery, two arteries from aorta with autologous venous tissue, open approach.
02110AW	Bypass coronary artery, two arteries from aorta with autologous arterial tissue, open approach.
021149W	Bypass coronary artery, two arteries from aorta with autologous venous tissue, percutaneous endoscopic approach.
02114AW	Bypass coronary artery, two arteries from aorta with autologous arterial tissue, percutaneous endoscopic approach.
021209W	Bypass coronary artery, three arteries from aorta with autologous venous tissue, open approach.
02120AW	Bypass coronary artery, three arteries from aorta with autologous arterial tissue, open approach.
021249W	Bypass coronary artery, three arteries from aorta with autologous venous tissue, percutaneous endoscopic approach.
02124AW	Bypass coronary artery, three arteries from aorta with autologous arterial tissue, percutaneous endoscopic approach.
021309W	Bypass coronary artery, four or more arteries from aorta with autologous venous tissue, open approach.
02130AW	Bypass coronary artery, four or more arteries from aorta with autologous arterial tissue, open approach.
021349W	Bypass coronary artery, four or more arteries from aorta with autologous venous tissue, percutaneous endoscopic approach.
02134AW	Bypass coronary artery, four or more arteries from aorta with autologous arterial tissue, percutaneous endoscopic approach.

This resulted in potential cases spanning 98 MS–DRGs, with approximately 93 percent of all potential cases, 59,139, mapping to the following 10 MS–DRGs:

MS–DRG	MS–DRG title
MS–DRG 3	Extracorporeal Membrane Oxygenation (ECMO) or Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth & Neck with Major Operating Room.
MS–DRG 216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.
MS–DRG 219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.
MS–DRG 220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.
MS–DRG 228	Other Cardiothoracic Procedures with MCC.
MS–DRG 229	Other Cardiothoracic Procedures without CC.
MS–DRG 233	Coronary Bypass with Cardiac Catheterization with MCC.
MS–DRG 234	Coronary Bypass with Cardiac Catheterization without MCC.
MS–DRG 235	Coronary Bypass without Cardiac Catheterization with MCC.
MS–DRG 236	Coronary Bypass without Cardiac Catheterization without MCC.

Using the 59,139 identified cases, the average case-weighted unstandardized charge per case was $200,886. The applicant then standardized the charges. The applicant did not remove charges for any current treatment because, as

discussed above, the applicant indicated there are no other current treatment options available. The applicant noted that it did not provide an inflation factor to project future charges. The applicant added charges for the DURAGRAFT® technology. This charge was created by applying the national average CCR for implantable devices of 0.332 from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38103) to the cost of the device. According to the applicant, no further charges or related charges were added. Based on the FY 2018 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $164,620. The final average case-weighted standardized charge per case was $185,575. Because the final 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 DURAGRAFT® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the substitutional use of DURAGRAFT® significantly reduces clinical complications associated with VGF following CABG surgery.

According to the applicant, DURAGRAFT® provides a benefit by protecting vascular grafts and their fragile luminal endothelial layer from the point of harvest until the point of grafting; an intra-operative ischemic interval lasting from about 10 minutes to 3 hours depending on the complexity of the surgery. According to the applicant, there are currently no products available to protect vascular grafts during this time interval. The current standard practice is to place grafts in heparinized saline or heparinized autologous blood to keep them wet; a practice which has been shown to cause significant damage to the graft within minutes, and which has been shown to clinically and statistically correlate with the development of 12-month VGF.[107] [108] [109] [110] Therefore, neglecting to protect the endothelial layer prior to implantation can have long-term consequences.

When a damaged luminal surface (endothelium) of a vascular graft is presented to the bloodstream at the time of reperfusion, a domino-effect of further damage is triggered *in vivo* through inflammatory, thrombogenic, and aberrant adaptive responses including hyper-proliferative processes that lead to VGF. These pathophysiologic responses occur within minutes of reperfusion of a graft that has received sub-optimal treatment/handling initiating a cascade of exacerbating damage that can continue for years later. Presenting an intact functional endothelial layer at the time of grafting is, therefore, tantamount to protecting the graft from damage that occurs post-grafting, in turn conferring protection against graft failure. Given the low success rate of failed graft intervention addressing the graft, endothelial protection at the time of surgery is critical.[111]

The combined PREVENT IV sub-analyses of Hess and Harskamp demonstrate that from dozens of factors evaluated for impact on the development of 12-month VGF, exposure to solutions used for intra-operative graft wetting and storage have the largest correlation with the development of VGF.[112, 113] Short-term exposure of free vascular grafts to these solutions is routine in CABG operations, where 10 minutes to 3 hours may elapse between the vein harvest and reperfusion.[114, 115] According to the applicant, standard of care solutions are heparinized saline and heparinized autologous blood, which were never designed to protect vascular grafts and have also demonstrated an inability to protect against ischemic injury, actively harming the graft endothelium as well.[116] [117] [118] [119] According to the applicant, given the criticality of presenting an intact functional endothelium at the time of reperfusion, it should not be surprising that the use of these solutions is so highly associated with 12-month VGF. Based on these data, DURAGRAFT® treatment has been designed to be a fully protective solution. DURAGRAFT® is formulated into a flushing, wetting, and storage solution replacing solutions traditionally used for this purpose and, therefore, does not change surgical practice.

The applicant noted that retrospective studies designed to assess clinical effectiveness and safety were conducted based on the readily available databases already in existence as a result of the use of DURAGRAFT® treatment in two hospitals that had noncommercial access to the product through hospital pharmacies. These studies evaluated the effect of DURAGRAFT® use during CABG surgery on post-CABG clinical complications associated with VGF, including myocardial infarction (MI) and repeat revascularization. The applicant conveyed that because of the time, resources and funding required for randomized studies evaluating clinical outcomes following CABG surgery, conducting such a study was not a viable approach for a small company such as Somahlution.

The first retrospective study (Protocol 001), an unpublished, independent Physician Investigator (PI), single-center, multi-surgeon retrospective,

[107] Harskamp, Ralf E., MD, Alexander, John H., MD, MHS, Schulte, Phillip J., Phd, et al., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery: follow-up from the PREVENT IV randomized clinical trial'', *Jama Surg,* 2014, vol. 149(8), pp. 798–805.

[108] Weiss, D.R., Juchem, G., Kemkes, B.M., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' Century Publishing Corporation, *International Journal of Clinical Experimental Medicine,* 2009 May 28, vol. 2(2), pp. 95–113.

[109] Wilbring, M., Tugtekin, S.M., Zatschler, B., et al., ''Even short-time storage in physiological saline solution impairs endothelial vascular function of saphenous vein grafts,'' Elsevier Science Inc., *European Journal of Cardio-Thoracic Surgery,* 2011 Oct, vol. 40(4), pp. 811–815.

[110] Thatte, H.S., Biswas, K.S., Najjar, S.F., et al., ''Multi-photon microscopic evaluation of saphenous vein endothelium and its preservation with a new solution,'' GALA, Elsevier Science Inc., *Ann Thorac Surg,* 2003 Apr, vol. 75(4), pp. 1145–1152.

[111] Kim, F.Y., Marhefka, G., Ruggiero, N.J., et al., ''Saphenous vein graft disease: review of pathophysiology, prevention, and treatment,'' *Cardiol* Rev 2013, vol. 21(2), pp. 101–9.

[112] Harskamp, Ralf E., MD, Alexander, John H., MD, MHS, Schulte, Phillip J., Phd, et al., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery: follow-up from the PREVENT IV randomized clinical trial'', *Jama Surg,* 2014, vol. 149(8), pp. 798–805.

[113] Testa, L., Bedogni, F., ''Treatment of Saphenous Vein Graft Disease: 'Never Ending Story' of the Eternal Return,'' *Res Cardiovasc Med,* 2014, vol. 3(3), pp. e21092.

[114] Motwani, J.G., Topol, E.J., ''Aortocoronary saphenous vein graft disease: pathogenesis, predisposition and prevention,'' *Circulation* 1998, vol. 97(9), pp. 916–31.

[115] Mills, N.L., Everson, C.T., ''Vein graft failure,'' *Curr Opin Cardiol,* 1995, vol. 10, pp. 562–8.

[116] Harskamp, Ralf E., MD, Alexander, John H., MD, MHS, Schulte, Phillip J., Phd, et al., ''Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery: follow-up from the PREVENT IV randomized clinical trial,'' *Jama Surg,* 2014, vol. 149(8), pp. 798–805.

[117] Weiss, D.R., Juchem, G., Kemkes, B.M., et al., ''Extensive deendothelialization and thrombogenicity in routinely prepared vein grafts for coronary bypass operations: facts and remedy,'' Century Publishing Corporation, *International Journal of Clinical Experimental Medicine,* 2009 May 28, vol. 2(2), pp. 95–113.

[118] Wilbring, M., Tugtekin, S.M., Zatschler, B., et al., ''Even short-time storage in physiological saline solution impairs endothelial vascular function of saphenous vein grafts,'' Elsevier Science Inc., *European Journal of Cardio-Thoracic Surgery,* 2011 Oct, vol. 40(4), pp. 811–815.

[119] Thatte, H.S., Biswas, K.S., Najjar, S.F., et al., ''Multi-photon microscopic evaluation of saphenous vein endothelium and its preservation with a new solution,'' GALA, Elsevier Science Inc., *Ann Thorac Surg,* 2003 Apr, vol. 75(4), pp. 1145–1152.

comparative study (DURAGRAFT® vs. Saline or Blood Solutions), was a pilot study conducted at the University of CHU in Angers France, which followed patients for 5 years post-CABG surgery. This pilot study was conducted to assess the safety and effect of DURAGRAFT® treatment on both short and long-term clinical outcomes. This study also served as the basis for the design of a larger retrospective study conducted at the U.S. Department of Veterans Affairs (VA) Medical Centers, discussed later. The objective of this single-center clinical study in CABG patients was to evaluate the potential benefits of DURAGRAFT® treatment as compared to a no-treatment control group (saline). The investigator who prepared the analysis remained blinded to individual patient data. Eligibility criteria included patients with first-time CABG surgery in which at least one vein graft was used. Patients with in-situ internal mammary artery (IMA) graft(s) only (no saphenous vein or free arterial grafts) and concomitant valve surgery and/or aortic aneurysm repair were excluded. The institutional review board of the University Health Alliance (UHA) approved the protocol, and patients gave written informed consent for their follow-up. A total of 630 patients who underwent elective and isolated CABG surgery with at least one saphenous vein graft at a single-center in Europe between January 2002 and December 2008 were included. The no-treatment control group (saline) included 375 patients who underwent CABG surgery from January 2002 to May 2005 and the DURAGRAFT® treatment group included 255 patients who underwent CABG surgery from June 2005 to December 2008. At long-term follow-up (greater than 30 days and up to 5 years), 5 patients were lost to follow-up (10 died before the 30-day follow-up). Therefore, a total of 247 patients from the DURAGRAFT® treatment group (97 percent) and 368 patients from the no-treatment control group (saline) (98 percent) were available for the long-term analysis. Patients undergoing CABG surgery whose vascular grafts were treated intraoperatively with DURAGRAFT® demonstrated no statistically significant differences in major adverse cardiac events (MACE) within the first 30 days following CABG surgery. According to the applicant, these data suggest that DURAGRAFT® treatment is at least as safe as the standard of care used in CABG surgeries in that long-term outcomes between the two groups were not statistically different. However, also according to the applicant, a consistent numerical trend toward improved clinical effectiveness outcomes for the DURAGRAFT® treatment group compared to the no-treatment control (saline) group was clearly identified. Although statistically insignificant, there was a consistent reduction observed in the rates for multiple endpoints such as all-cause death, MI, MACE, and revascularization. This study found reductions in DURAGRAFT®-treated grafts relative to saline for revascularization (57 percent), MI (70 percent), MACE (37 percent) and all-cause death (23 percent) compared to standard of care (heparinized saline/blood) through 5 years follow-up. Based on the small sample-size for this evaluation of only 630 patients, and the known frequencies of these events following CABG surgeries, statistical differences were not expected. A subsequent post-hoc analysis also was performed by the researchers at CHU-Angers to evaluate whether any long-term clinical variables (such as dual antiplatelet therapy, beta-blockers, angiotensin receptor-blockers, statins, diabetes, lifestyle and other factors) had any impact on the study endpoints. The conclusions of the post-hoc analyses were that the assessed clinical variables did not impact the clinical study findings and so any differences between groups were likely due to ''test article'' effect. According to the applicant, importantly, the data collected from this feasibility study are consistent with data collected in the statistically-powered VA study in which statistically significant reductions of MI, repeat revascularization, and MACE were observed in the DURAGRAFT® treatment group, lending confidence that the observed trends in this study, as well as the VA study, represent real differences associated with DURAGRAFT® use.

The second study, the U.S. VA Hospital Study (Protocol 002), was an unpublished, independent PI initiated, single-center, multi-surgeon, retrospective, comparative (DURAGRAFT® vs. Saline) clinical trial, which was conducted to assess the safety and impact of DURAGRAFT® treatment on both short and long-term clinical outcomes in patients who underwent isolated CABG surgery with saphenous vein grafts (SVGs) at the Boston (West Roxbury) VA Medical Center between 1996 and 2004. The time interval from 1996 through 1999 represents a time period when DURAGRAFT® treatment was not available and heparinized saline was routinely used to wet and store grafts, while 2001 through 2004 represents a time period after the center began exclusively using DURAGRAFT®, which was prepared by the hospital's pharmacy. The year 2000 was omitted from this analysis by the PI due to the transition of the implementation of DURAGRAFT® treatment into the clinic and the uncertainty of its use in CABG patients during the transition period. Data were extracted from a total of 2,436 patients who underwent a CABG procedure with at least one SVG from 1996 through 1999 (Control n=1,400 pts.) and 2001 through 2004 (DURAGRAFT® treatment n=1,036 pts.). The median age was 66 years old for the control treatment group and 67 years old for the DURAGRAFT® treatment group. Patients were excluded from the study if they had a prior history of CABG procedures, had no use of SVG, or underwent additional procedures during the CABG surgery. Mean follow-up in the DURAGRAFT® treatment group was 8.5±4.2 years and 9.9±5.6 years in the control treatment group. According to the applicant, this study supports not only safety, but also improved long-term clinical outcomes in DURAGRAFT®-treated CABG patients. Thirty-day MI also was significantly reduced in this study. The VA study found statistically significant reductions in DURAGRAFT®-treated grafts relative to saline for revascularization (35 percent), MI (45 percent), and MACE (19 percent) from the follow-up period of 1,000 days to 15 years post-surgery.

According to the applicant, in addition to the retrospective studies, a multi-center, within-patient randomized, prospective study utilizing multidetector computed tomography (MDCT) angiography was conducted to assess safety and the effect of the use of DURAGRAFT® on the graft by assessing early anatomic markers of VGD such as graft wall thickening and early stenotic events. The study was based on an ''in-patient control'' design in which both the control saline exposed vascular graft and a DURAGRAFT®-treated graft were grafted within the same patient to reduce patient bias and allow a paired analysis of the grafts. The study was conducted under two protocols. The first study protocol evaluated patients up to 3 months post-CABG and included 1- and 3-month protocol driven MDCT scans in 125 patients (250 grafts). The second study, a longer-term safety and efficacy study of 97 patients, included a 12-month protocol driven angiogram. The 3 month (full data set) and 12 month (interim data set) data demonstrate that safety and efficacy appear to be equivalent for

DURAGRAFT® and standard of care (SoC) at 3 months, but between 3 months and 9 months a separation between DURAGRAFT® and SoC begins to emerge and by 12 months DURAGRAFT® use is associated with a numerical trend towards improved safety relative to SoC. Furthermore by 12 months, the interim analysis demonstrated that differences in markers of early graft disease were able to be discerned between DURAGRAFT®-treated grafts and SoC. Reductions in both wall thickness and degree of stenosis were observed in DURAGRAFT®-treated grafts relative to SoC grafts. These reductions were observed when the entire graft was assessed and were more profound when the proximal region of the graft was specifically evaluated. According to the applicant, this is of note because the proximal region of the graft is the region in which early graft disease has been shown to more frequently manifest in many grafting indications, including CABG, peripheral bypass, aortic grafting, and AV fistula grafting indications, and is thought to be due to hemodynamic perturbations that occur in this region where arterial flow is just entering the venous environment. While there are no notable differences at 3 months in either safety or efficacy, there are trends towards better safety at 12 months in patients in the DURAGRAFT® treatment group compared to the control group.[120] The efficacy results of the prospective study were presented at the October 2017 meeting of the TCT Congress in Denver.

The retrospective studies demonstrated an association of reduced risk of non-fatal myocardial infarction, repeat revascularization, and MACE with DURAGRAFT® treatment. However, we have a number of concerns relating to these studies. In addition to the studies being unpublished, we are concerned that they leave too many variables unaccounted for that could affect vein integrity such as method of vein harvest, vein distention pressure, and post-operative care (including use of anti-platelet and anti-lipid treatments). Also, control groups underwent CABG procedures many years earlier than the DURAGRAFT® treatment groups in both studies. Over the years, with advances in medical management and surgical techniques, long-term survival and risk of cardiac events are expected to improve. Finally, it may be helpful to gain more insight from data that will be available upon completion and results of the multi-center, prospective, randomized, double-blind, comparative, within-person (DURAGRAFT® vs. Saline) control trial that is currently ongoing.

We are inviting public comments on whether DURAGRAFT® meets the substantial clinical improvement criterion.

Below we summarize and respond to written public comments we received regarding the DURAGRAFT® during the open comment period in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: One commenter, a cardiothoracic surgeon, stated that after practicing cardiac surgery for over 30 years, authoring peer-reviewed publications in *Cardiac Surgery,* and participating in several clinical studies, it supported the approval of new technology add-on payments for the DURAGRAFT® technology. The commenter indicated that one of the reasons why vein grafts get occluded could be because of poor handling during and after harvest. The commenter expressed that there are currently no other solutions used in treatment options available that protect vascular conduits once they are harvested aside from the standard practice of storing them in saline or blood-based solutions until they are ready for implantation. The commenter stated that saline and blood-based solutions are very damaging to vein segments, and the damage that occurs is linked to poor clinical outcomes including increased risk of myocardial infarction (MI) and increased rates of repeat revascularization. The commenter indicated that it had many years of first-hand experience with the use of DURAGRAFT® because the commenter served as the Principal Investigator for a retrospective clinical study that evaluated the DURAGRAFT®'s effect on clinical outcomes compared to standard-of-care treatment options. The commenter conveyed that the results of the retrospective clinical study included statistically significant reductions in MI and repeat revascularization rates. The commenter also pointed out its awareness of a prospective clinical study the DURAGRAFT®'s manufacturer has conducted evaluating radiologic assessments to analyze graft disease, which precedes loss of patency. According to the commenter, the study demonstrated increased wall thickness and increased stenosis in grafts stored in saline compared to grafts stored using the DURAGRAFT®. The commenter stated that this finding from the prospective clinical study is very consistent with the clinical results of the retrospective study. The commenter concluded by stating that it supported the commercial availability and use of the DURAGRAFT®, including use in the treatment of its own patients.

Response: We appreciate the commenter's input. We will take these comments into consideration when deciding whether to approve new technology add-on payment for the DURAGRAFT® for FY 2019.

Comment: Another commenter, a cardiovascular and thoracic surgeon with clinical expertise in coronary artery bypass grafting surgery (CABG) who has been involved in endothelial dysfunction as a primary field of study and the Principal Investigator for the multi-center, within-patient, randomized, prospective study that Somahlution submitted to the FDA in support of U.S. product clearance, supported the approval of new technology add-on payments for the DURAGRAFT®. The commenter indicated that as an author and co-author of more than 250 articles in peer-reviewed publications, a senior author of more than 75 papers and writer of several book chapters, and having delivered over 40 conference presentations worldwide, the study results, specifically of the 12-month multidector computed tomography (MDCT) imaging showing less lumen narrowing or stenosis, and less wall thickening as a resulting outcome of the DURAGRAFT®-treated veins compared to heparinized-saline, are critically important from a clinical perspective. According to the commenter, the primary mechanism of the DURAGRAFT® technology is to protect the endothelial cells in the vein graft and this has been repeatedly demonstrated in pre-clinical studies. The commenter explained that the findings of the clinical anatomic changes in the graft demonstrated in the prospective study are consistent with the pre-clinical findings and the literature that has clearly pointed to damaged endothelium of the graft as the starting insult for later development of poor patient outcomes from graft disease and failure. Finally, the commenter noted that surgeons in all countries currently use a variety of graft storage and preservation solutions during a CABG procedure because there has been no other available solution used in treatment options, aside from the DURAGRAFT®, with systematic evaluation demonstrating a clear safety

[120] Perrault, L., ''SOMVC001 (DuraGraft) Vascular Graft Treatment in Patients Undergoing Coronary Artery Bypass Grafting,'' American Heart Association, Inc, *Circulation,* 2016, vol. 134, pp. A23242, originally published November 11, 2016.

profile and benefit to patient outcomes. The commenter encouraged CMS to approve new technology add-on payments for the DURAGRAFT® technology to provide additional support for this new preservation solution to become available to surgeons in the United States.

Response: We appreciate the commenter's input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for DURAGRAFT® for FY 2019.

e. remedē® System

Respicardia, Inc. submitted an application for new technology add-on payments for the remedē® System for FY 2019. According to the applicant, 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. The remedē® System consists of an implantable pulse generator, and a stimulation and sensing lead. The pulse generator is placed under the skin, in either the right or left side of the chest, and it functions to monitor the patient's respiratory signals. A transvenous lead for unilateral stimulation of the phrenic nerve is placed either in the left pericardiophrenic vein or the right brachiocephalic vein, and a second lead to sense respiration is placed in the azygos vein. Both leads, in combination with the pulse generator, function to sense respiration and, when appropriate, generate an electrical stimulation to the left or right phrenic nerve to restore regular breathing patterns.

The applicant's application describes central sleep apnea (CSA) as a chronic respiratory disorder characterized by fluctuations in respiratory drive, resulting in the cessation of respiratory muscle activity and airflow during sleep.[121] The applicant reported that CSA, as a primary disease, has a low prevalence in the United States population; and it is more likely to occur in those individuals who have cardiovascular disease, heart failure, atrial fibrillation, stroke, or chronic opioid usage. The apneic episodes which occur in patients with CSA cause hypoxia, increased blood pressure, increased preload and afterload, and promotes myocardial ischemia and arrhythmias. In addition, CSA ''enhances oxidative stress, causing endothelial dysfunction, inflammation, and activation of neurohormonal systems, which contribute to progression of underlying diseases.'' [122]

According to the applicant, prior to the introduction of the remedē® System, typical treatments for CSA took the form of positive airway pressure devices. Positive airway pressure devices, such as continuous positive airway pressure (CPAP), have previously been used to treat patients diagnosed with obstructive sleep apnea. Positive airway devices deliver constant pressurized air via a mask worn over the mouth and nose, or nose alone. For this reason, positive airway devices may only function when the patient wears the necessary mask. Similar to CPAP, adaptive servo-ventilation (ASV) provides noninvasive respiratory assistance with expiratory positive airway pressure. However, ASV adds servo-controlled inspiratory pressure, as well, in an effort to maintain airway patency.[123]

On October 6, 2017, the remedē® System was approved by the FDA as an implantable phrenic nerve stimulator indicated for the use in the treatment of adult patients who have been diagnosed with moderate to severe CSA. The device was available commercially upon FDA approval. Therefore, the newness period for the remedē® System is considered to begin on October 6, 2017. The applicant has indicated that the device also is designed to restore regular breathing patterns in the treatment of CSA in patients who also have been diagnosed with heart failure.

The applicant was approved for two unique ICD–10–PCS procedure codes for the placement of the leads: 05H33MZ (Insertion of neurostimulator lead into right innominate (brachiocephalic) vein) and 05H03MZ (Insertion of neurostimulator lead into azygos vein), effective 10/01/2016. The applicant indicated that implantation of the pulse generator is currently reported using ICD–10–PCS procedure code 0JH60DZ (Insertion of multiple array stimulator generator into chest subcutaneous tissue).

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 the 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, the remedē® System provides stimulation to nerves to stimulate breathing. Typical treatments for hyperventilation CSA include supplemental oxygen and CPAP. Mechanical ventilation also has been used to maintain a patent airway. The applicant asserted that the remedē® System is a neurostimulation device resulting in negative airway pressure, whereas devices such as CPAP and ASV utilize positive airway pressure.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the remedē® System is assigned to MS–DRGs 040 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC), 041 (Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator), and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC). The current procedures for the treatment options of CPAP and ASV are not assigned to these MS–DRGs.

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 remedē® System is indicated for the use as a transvenous unilateral phrenic nerve stimulator in the treatment of adult patients who have been diagnosed with moderate to severe CSA. The applicant stated that the remedē® System reduces the negative symptoms associated with CSA, particularly among patients who have been diagnosed with heart failure. The applicant asserted that patients who have been diagnosed with heart failure are particularly negatively affected by CSA and currently available CSA treatment options of CPAP and ASV. According to the applicant, the currently available treatment options, CPAP and ASV, have been found to have worsened mortality and morbidity outcomes for patients who have been diagnosed with both CSA and heart failure. Specifically, ASV is currently contraindicated in the treatment of CSA in patients who have been diagnosed with heart failure.

The applicant also suggested that the remedē® System is particularly suited for the treatment of CSA in patients who

[121] Jagielski, D., Ponikowski, P., Augostini, R., Kolodziej, A., Khayat, R., Abraham, W.T., 2016, ''Transvenous Stimulation of the Phrenic Nerve for the Treatment of Central Sleep Apnoea: 12 months' experience with the remede®system,'' *European Journal of Heart Failure,* pp. 1–8.

[122] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T., ''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lancet,* 2016, vol. 388, pp. 974–982.

[123] Cowie, M.R., Woehrle, H., Wegscheider, K., Andergmann, C., d'Ortho, M.P., Erdmann, E., Teschler, H., ''Adaptive Servo-Ventilation for Central Sleep Apneain Systolic Heart Failure,'' *N Eng Jour of Med,* 2015, pp. 1–11.

also have been diagnosed with heart failure. We are concerned that, while the remedē® System may be beneficial to patients who have been diagnosed with both CSA and heart failure, the FDA approved indication is for use in the treatment of adult patients who have been diagnosed with moderate to severe CSA. We note that the applicant's clinical analyses and data results related to patients who specifically were diagnosed with CSA and heart failure. We are inviting public comments on whether the remedē® System meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate that the technology meets the cost criterion. The applicant identified cases representing potential patients who may be eligible for treatment involving the remedē® System within MS–DRGs 040, 041, and 042. Using the Standard Analytical File (SAF) Limited Data Set (MedPAR) for FY 2015, the applicant included all claims for the previously stated MS–DRGs for its cost threshold calculation. The applicant stated that typically claims are selected based on specific ICD–10–PCS parameters, however this is a new technology for which no ICD–10–PCS procedure code and ICD–10–CM diagnosis code combination exists. Therefore, all claims for the selected MS–DRGs were included in the cost threshold analysis. This process resulted in 4,462 cases representing potential patients who may be eligible for treatment involving the remedē® System assigned to MS–DRG 040; 5,309 cases representing potential patients who may be eligible for treatment involving the remedē® System assigned to MS–DRG 041; and 2,178 cases representing potential patients who may be eligible for treatment involving the remedē® System assigned to MS–DRG 042, for a total of 11,949 cases.

Using the 11,949 identified cases, the applicant determined that the average unstandardized case-weighted charge per case was $85,357. Using the FY 2015 MedPAR dataset to identify the total mean charges for revenue code 0278, the applicant removed charges associated with the current treatment options for each MS–DRG as follows: $9,153.83 for MS–DRG 040; $12,762.31 for MS–DRG 041; and $21,547.73 for MS–DRG 042. The applicant anticipated that no other related charges would be eliminated or replaced. The applicant then standardized the charges and applied a 2-year inflation factor of 1.104055 obtained from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524). The applicant then added charges for the new technology to the inflated average case-weighted standardized charges per case. No other related charges were added to the cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $175,329 and a Table 10 average case-weighted threshold amount of $78,399. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. With regard to the analysis above, we are concerned that all cases in MS–DRGs 040, 041, and 042 were used in the analysis. We are unsure if all of these cases represent patients that may be truly eligible for treatment involving the remedē® System. We are inviting public comments on whether the remedē® System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the remedē® System meets the substantial clinical improvement criterion. The applicant stated that the remedē® System offers a treatment option for a patient population unresponsive to, or ineligible for, treatment involving currently available options. According to the applicant, patients who have been diagnosed with CSA have no other available treatment options than the remedē System. The applicant stated that published studies on both CPAP and ASV have proven that primary endpoints have not been met for treating patients who have been diagnosed with CSA. In addition, according to the ASV study, there was an increase in cardiovascular mortality.

According to the applicant, the remedē® System will prove to be a better treatment for the negative effects associated with CSA in patients who have been diagnosed with heart failure, such as cardiovascular insults resulting from sympathetic nervous system activation, pulmonary hypertension, and arrhythmias, which ultimately contribute to the downward cycle of heart failure,[124] when compared to the currently available treatment options. The applicant also indicated that prior studies have assessed CPAP and ASV as options for the treatment of diagnoses of CSA primarily in patients who have been diagnosed with heart failure.

The applicant shared the results from two studies concerning the effects of positive airway pressure ventilation treatment:

- The Canadian Continuous Positive Airway Pressure for Patients with Central Sleep Apnea and Heart Failure trial found that, while CPAP managed the negative symptoms of CSA, such as improved nocturnal oxygenation, increased ejection fraction, lower norepinephrine levels, and increased walking distance, it did not affect overall patient survival; [125] and
- In a randomized trial of 1,325 patients who had been diagnosed with heart failure who received treatment with ASV plus standard treatment or standard treatment alone, ASV was found to increase all-cause and cardiovascular mortality as compared to the control treatment.[126]

The applicant also stated that published literature indicates that currently available treatment options do not meet primary endpoints with concern to the treatment of CSA; patients treated with ASV experienced an increased likelihood of mortality,[127] and patients treated with CPAP experienced alleviation of symptoms, but no change in survival.[128] The applicant provided further research, which suggested that a primary drawback of CPAP in the treatment of diagnoses of CSA is a lack of patient adherence to therapy.[129]

The applicant also stated that the remedē System represents a substantial clinical improvement over existing technologies because of the reduction in the number of future hospitalizations, few device-related complications, and improvement in CSA symptoms and quality of life. Specifically, the applicant stated that the clinical data has shown a statistically significant reduction in Apnea-hypopnea index (AHI), improvement in quality of life, and significantly improved Minnesota Living with Heart Failure Questionnaire score. In addition, the applicant

[124] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

[125] Bradley, T.D., Logan, A.G., Kimoff, R.J., Series, F., Morrison, D., Ferguson, K., Phil, D., 2005, ''Continous Positive Airway Pressure for Central Sleep Apnea and Heart Failure,'' *N Eng Jour of Med,* vol. 353(19), pp. 2025–2033.

[126] Cowie, M.R., Woehrle, H., Wegscheider, K., Andergmann, C., d'Ortho, M.-P., Erdmann, E., Teschler, H., ''Adaptive Servo-Ventilation for Central Sleep Apneain Systolic Heart Failure,'' *N Eng Jour of Med,* 2015, pp. 1–11.

[127] Ibid.

[128] Bradley, T.D., Logan, A.G., Kimoff, R.J., Series, F., Morrison, D., Ferguson, K., Phil, D., 2005, ''Continous Positive Airway Pressure for Central Sleep Apnea and Heart Failure,'' *N Engl Jour of Med,* vol. 353(19), pp. 2025–2033.

[129] Ponikowski, P., Javaheri, S., Michalkiewicz, D., Bart, B.A., Czarnecka, D., Jastrzebski, M., Abraham, W.T., ''Transvenous Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnoea in Heart Failure,'' *European Heart Journal,* 2012, vol. 33, pp. 889–894.

indicated that study results showed the remedē System demonstrated an acceptable safety profile, and there was a trend toward fewer heart failure hospitalizations.

The applicant provided six published articles as evidence. All six articles were prospective studies. In three of the six studies, the majority of patients studied had been diagnosed with CSA with a heart failure comorbidity, while the remaining three studies only studied patients who had been diagnosed with CSA with a heart failure comorbidity. The first study [130] assessed the treatment of patients who had been diagnosed with CSA in addition to heart failure. According to the applicant, as referenced in the results of the published study, Ponikowski, et al., assessed the treatment effects of 16 of 31 enrolled patients with evidence of CSA within 6 months prior to enrollment who met inclusion criteria (apnea-hypopnea index of greater than or equal to 15 and a central apnea index of greater than or equal to 5) and who did not meet exclusion criteria (a baseline oxygen saturation of less than 90 percent, being on supplemental oxygen, having evidence of phrenic nerve palsy, having had severe chronic obstructive pulmonary disease (COPD), having hard angina or a myocardial infarction in the past 3 months, being pacemaker dependent, or having inadequate capture of the phrenic nerve during neurostimulation). Of the 16 patients whose treatment was assessed, all had various classifications of heart failure diagnoses: 3 (18.8 percent) were classified as class I on the New York Heart Association classification scale (No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)); 8 (50 percent) were classified as a class II (Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath)); and 5 (31.3 percent) were classified as class III (Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea).[131] After successful surgical implantation of a temporary transvenous lead for unilateral phrenic nerve stimulation, patients underwent a control night without nerve stimulation and a therapy night with stimulation, while undergoing polysomnographic (PSG) testing. Comparison of both nights was performed.

According to the applicant, some improvements of CSA symptoms were identified in statistical analyses. Sleep time and efficacy were not statistically significantly different for control night and therapy night, with median sleep times of 236 minutes and 245 minutes and sleep efficacy of 78 percent and 71 percent, respectively. There were no statistical differences across categorical time spent in each sleep stage (for example, N1, N2, N3, and REM) between control and therapy nights. The average respiratory rate and hypopnea index did not differ statistically across nights. Marginal positive statistical differences occurred between control and therapy nights for the baseline oxygen saturation median values (95 and 96 respectively) and obstructive apnea index (OAI) (1 and 4, respectively). Beneficial statistically significant differences occurred from control to therapy nights for the average heart rate (71 to 70, respectively), arousal index events per hour (32 to 12, respectively), apnea-hypopnea index (AHI) (45 to 23, respectively), central apnea index (CAI) (27 to 1, respectively), and oxygen desaturation index of 4 percent (ODI = 4 percent) (31 to 14, respectively). Two adverse events were noted: (1) Lead tip thrombus noted when lead was removed; the patient was anticoagulated without central nervous system sequelae; and (2) an episode of ventricular tachycardia upon lead placement and before stimulation was initiated. The episode was successfully treated by defibrillation of the patient's implanted ICD. Neither adverse event was directly related to the phrenic nerve stimulation therapy.

The second study [132] was a prospective, multi-center, nonrandomized study that followed patients diagnosed with CSA and other underlying comorbidities. According to the applicant, as referenced in the results of the published study, Abraham, et al., 49 of the 57 enrolled patients who were followed indicated a primary endpoint of a reduction of AHI with secondary endpoints of feasibility and safety of the therapy. Patients were included if they had an AHI of 20 or greater and apneic events that were related to CSA. Among the study patient population, 79 percent had diagnoses of heart failure, 2 percent had diagnoses of atrial fibrillation, 13 percent had other cardiac etiology diagnoses, and the remainder of patients had other cardiac unrelated etiology diagnoses. Exclusion criteria were similar to the previous study (that is, (Ponikowski P., 2012)), with the addition of a creatinine of greater than 2.5 mg/dl. After implantation of the remedē® System, patients were assessed at baseline, 3 months (n=47) and 6 months (n=44) on relevant measures. At 3 months, statistically nonsignificant results occurred for the OAI and hypopnea index (HI) measures. The remainder of the measures showed statistically significant differences from baseline to 3 months: AHI with a −27.1 episodes per hour of sleep difference; CAI with a −23.4 episodes per hour of sleep difference; MAI with a −3 episodes per hour of sleep difference; ODI = 4 percent with a −23.7 difference; arousal index with −12.5 episodes per hour of sleep difference; sleep efficiency with a 8.4 percent increase; and REM sleep with a 4.5 percent increase. Similarly, among those assessed at 6 months, statistically significant improvements on all measures were achieved, including OAI and HI. Regarding safety, a data safety monitoring board (DSMB) adjudicated and found the following 3 of 47 patients (6 percent) as having serious adverse events (SAE) related to the device, implantation procedure or therapy. None of the DSMB adjudicated SAEs was due to lead dislodgement. Two SAEs of hematoma or headache were related to the implantation procedure and occurred as single events in two patients. A single patient experienced atypical chest discomfort during the first night of stimulation, but on reinitiation of therapy on the second night no further discomfort occurred.

The third study [133] assessed the safety and feasibility of phrenic nerve stimulation for 6 monthly follow-ups of 8 patients diagnosed with heart failure with CSA. Of the eight patients assessed, one was lost to follow-up and one died from pneumonia. According to the applicant, as referenced in the results in the published study, Zheng, et al. (2015), no unanticipated serious adverse events were found to be related to the therapy; in one patient, a lead became dislodged and subsequently successfully repositioned. Three

[130] Ponikowski, P., Javaheri, S., Michalkiewicz, D., Bart, B.A., Czarnecka, D., Jastrzebski, M., Abraham, W.T., ''Transvenous Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnoea in Heart Failure,'' *European Heart Journal,* 2012, vol. 33, pp. 889–894.

[131] ''Classes of Heart Failure,'' 2017, May 8, Retrieved from American Heart Association: Available at: *http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp#.WmE2rlWnGUk.*

[132] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

[133] Zhang, X., Ding, N., Ni, B., Yang, B., Wang, H., & Zhang, S.J., 2015, ''Satefy and Feasibility of Chronic Transvenous Phrenic Nerve Stimulation for Treatment of Central Sleep Apnea in Heart Failure Patients,'' *The Clinical Respiratory Journal,* pp. 1–9.

patients reported improved sleep quality, and all patients reported increased energy. A reduction in sleep apneic events and decreases in AHI and CAI were related to application of the treatment. Gradual increases to the 6-minute walking time occurred through the study.

The fourth study [134] extended the previous Phase I study [135] from 6 months to 12 months, and included only 41 of the original 49 patients continuing in the study. Of the 57 patients enrolled at the time of the Phase I study, 41 were evaluated at the 12-month follow-up. Of the 41 patients examined at 12 months, 78 percent had diagnoses of CSA related to heart failure, 2 percent had diagnoses of atrial fibrillation with related CSA, 12 percent had diagnoses of CSA related to other cardiac etiology diagnoses, and the remainder of patients had diagnoses of CSA related to other noncardiac etiology diagnoses. At 12 months, 6 sleep parameters remained statistically different and 3 were no longer statistically significant. The HI, OAI, and arousal indexes were no longer statistically significantly different from baseline values. A new parameter, time spent with peripheral capillary oxygen saturation (SpO_2) below 90 percent was not statistically different at 12 months (31.4 minutes) compared to baseline (38.2 minutes). The remaining 6 parameters showed maintenance of improvements at the 12-month time point as compared to the baseline: AHI from 49.9 to 27.5 events per hour; CAI from 28.2 to 6.0 events per hour; MAI from 3.0 to 0.5 events per hour; ODI = 4 percent from 46.1 to 26.9 events per hour; sleep efficiency from 69.3 percent to 75.6 percent; and REM sleep from 11.4 percent to 17.1 percent. At the 3-month, 6-month, and 12-month time points, patient quality of life was assessed to be 70.8 percent, 75.6 percent, and 83.0 percent, respectively, indicating that patients experienced mild, moderate, or marked improvement. Seventeen patients were followed at 18 months with statistical differences from baseline for AHI and CAI. Three patients died over the 12-month follow-up period: 2 died of end-stage heart failure and 1 died from sudden cardiac death. All three deaths were adjudicated by the DSMB and none were related to the procedure or to phrenic nerve stimulation therapy. Five patients were found to have related serious adverse events over the 12-month study time. Three events were previously described in the results referenced in the published study, Abraham, et al., and an additional 2 SAEs occurred during the 12-month follow-up. One patient experienced impending pocket perforation resulting in pocket revision, and another patient experienced lead failure.

The fifth study [136] was a randomized control trial with a primary outcome of achieving a reduction in AHI of 50 percent or greater from baseline to 6 months enrolling 151 patients with the neurostimulation treatment (n=73) and no stimulation control (n=78). Of the total sample, 96 (64 percent) of the patients had been diagnosed with heart failure; 48 (66 percent) of the treated patients had been diagnosed with heart failure, and 48 (62 percent) of the control patients had been diagnosed with heart failure. Sixty-four (42 percent) of all of the patients included in the study had been diagnosed with atrial fibrillation and 84 (56 percent) had been diagnosed with coronary artery disease. All of the patients had been treated with the remedē® System device implanted; the system was activated in the treatment group during the first month. ''Over about 12 weeks, stimulation was gradually increased in the treatment group until diaphragmatic capture was consistently achieved without disrupting sleep.'' [137] While patients and physicians were unblinded, the polysomnography core laboratory remained blinded. The per-protocol population from which statistical comparisons were made is 58 patients treated with the remedē® System and 73 patients in the control group. The authors appropriately controlled for Type I errors (false positives), which arise from performing multiple tests. Thirty-five treated patients and 8 control patients met the primary end point, the number of patients with a 50 percent or greater reduction in AHI from baseline; the difference of 41 percent is statistically significant. All seven of the secondary endpoints were assessed and found to have statistically significant difference in change from baseline between groups at the 6-month follow-up after controlling for multiple comparisons: CAI of −22.8 events per hour lower for the treatment group; AHI (continuous) of −25.0 events per hour lower for the treatment group; arousal events per hour of −15.2 lower for the treatment group; percent of sleep in REM of 2.4 percent higher for the treatment group; patients with marked or moderate improvement in patient global assessment was 55 percent higher in the treatment group; ODI = 4 percent was −22.7 events per hour lower for the treatment group; and the Epworth sleepiness scale was −3.7 lower for the treatment group. At 12 months, 138 (91 percent) of the patients were free from device, implant, and therapy related adverse events.

The final study data was from the pivotal study with limited information in the form of an abstract [138] and an executive summary.[139] The executive summary detailed an exploratory analysis of the 141 patients enrolled in the pivotal trial which were patients diagnosed with CSA. The abstract indicated that the 141 patients from the pivotal trial were randomized to either the treatment arm (68 patients) in which initiation of treatment began 1 month after implantation of the remedē® System device with a 6-month follow-up period, or to the control group arm (73 patients) in which the initiation of treatment with the remedē® System device was delayed for 6 months after implantation. Randomization efficacy was compared across baseline polysomnography and associated respiratory indices in which four of the five measures showed no statistical differences between those treated and controls; treated patients had an average MAI score of 3.1 as compared to control patients with an average MAI score of 2.2 (p=0.029). Patients included in the trial must have been medically stable, at least 18 years old, have had an electroencephalogram within 40 days of scheduled implantation, had an apnoea-hypopnoea index (AHI) of 20 events per hour or greater, a central apnoea index at least 50 percent of all apneas, and an obstructive apnea index less than or equal to 20 percent.[140] Primary exclusion criteria were CSA caused by pain medication, heart failure of state D from the American Heart Association, a

[134] Jagielski, D., Ponikowski, P., Augostini, R., Kolodziej, A., Khayat, R., & Abraham, W.T., 2016, ''Transvenous Stimulation of the Phrenic Nerve for the Treatment of Central Sleep Apnoea: 12 months' experience with the remede®system,'' *European Journal of Heart Failure,* 2016, pp. 1–8.

[135] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., 2015, ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

[136] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T.,''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lancet,* 2016, vol. 388, pp. 974–982.

[137] Ibid.

[138] Goldberg, L., Ponikowski, P., Javaheri, S., Augostini, R., McKane, S., Holcomb, R., Costanzo, M.R., ''In Heart Failure Patients with Central Sleep Apnea, Transvenous Stimulation of the Phrenic Nerve Improves Sleep and Quality of Life,'' Heart Failure Society of America, 21st annual meeting. 2017.

[139] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[140] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

new implantable cardioverter defibrillator, pacemaker dependent subjects without any physiologic escape rhythm, evidence of phrenic nerve palsy, documented history of psychosis or severe bipolar disorder, a cerebrovascular accident within 12 months of baseline testing, limited pulmonary function, baseline oxygen saturation less than 92 percent while awake and on room air, active infection, need for renal dialysis, or poor liver function.[141] Patients included in this trial were primarily male (89 percent), white (95 percent), with at least one comorbidity with cardiovascular conditions being most prevalent (heart failure at 64 percent), with a concomitant implantable cardiovascular stimulation device in 42 percent of patients at baseline. The applicant stated that, after randomization, there were no statistically significant differences between the treatment and control groups, with the exception of the treated group having a statistically higher rate of events per hour on the mixed apnea index (MAI) at baseline than the control group.

The applicant asserted that the results from the pivotal trial [142] allow for the comparison of heart failure status in patients; we note that patients with American Heart Association objective assessment Class D (Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest) were excluded from this pivotal trial. The primary endpoint in the pivotal trial was the proportion of patients with an AHI reduction greater than or equal to 50 percent at 6 months. When controlling for heart failure status, both treated groups experienced a statistically greater proportion of patients with AHI reductions than the controls at 6 months (58 percent more of treated patients with diagnoses of heart failure and 35 percent more of treated patients without diagnoses of heart failure as compared to their respective controls). The secondary endpoints assessed were the CAI average events per hour, AHI average events per hour, arousal index (ArI) average events per hour, percent of sleep in REM, and oxygen desaturation index 4 percent (ODI = 4 percent) average events per hour. Excluding the percent of sleep in REM, the treatment groups for both patients with diagnoses of heart failure and non-heart failure conditions experienced statistically greater improvements at 6 months on all secondary endpoints as compared to their respective controls. Lastly, quality of life secondary endpoints were assessed by the Epworth sleepiness scale (ESS) average scores and the patient global assessment (PGA). For both the ESS and PGA assessments, both treatment groups of patients with diagnoses of heart failure and non-heart failure conditions had statistically beneficial changes between baseline and 6 months as compared to their respective control groups.

The applicant provided analyses from the above report focusing on the primary and secondary polysomnography endpoints, specifically, across patients who had been diagnosed with CSA with heart failure and non-heart failure. Eighty patients included in the study from the executive summary report had comorbid heart failure, while 51 patients did not. Of those patients with heart failure, 35 were treated while 45 patients were controls. Of those patients without heart failure, 23 were treated and 28 patients were controls. The applicant did not provide baseline descriptive statistical comparisons between treated and control groups controlling for heart failure status. Across all primary and secondary endpoints, the patient group who were diagnosed with CSA and comorbid heart failure experienced statistically significant improvements. Excepting percent of sleep in REM, the patient group who were diagnosed with CSA without comorbid heart failure experienced statistically significant improvements in all primary and secondary endpoints. We are inviting public comments on whether this current study design is sufficient to support substantial clinical improvement of the remedē® System with respect to all patient populations, particularly the non-heart failure population.

As previously noted, the applicant also contends that the technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment options. Specifically, the applicant stated that the remedē® System is the only treatment option for patients who have been diagnosed with moderate to severe CSA; published studies on positive pressure treatments like CPAP and ASV have not met primary endpoints; and there was an increase in cardiovascular mortality according to the ASV study. According to the applicant, approximately 40 percent of patients who have been diagnosed with CSA have heart failure. The applicant asserted that the use of the remedē System not only treats and improves the symptoms of CSA, but there is evidence of reverse remodeling in patients with reduced left ventricular ejection fraction (LVEF).

We are concerned that the remedē® System is not directly compared to the CPAP or ASV treatment options, which, to our understanding, are the current treatment options available for patients who have been diagnosed with CSA without heart failure. We note that the FDA indication for the implantation of the remedē® System is for use in the treatment of adult patients who have been diagnosed with CSA. We also note that the applicant's supporting studies were directed primarily at patients who had been treated with the remedē® System who also had been diagnosed with heart failure. The applicant asserted that it would not be appropriate to use CPAP and ASV treatment options when comparing CPAP and ASV to the remedē® System in the patient population of heart failure diagnoses because these treatment options have been found to increase mortality outcomes in this population. In light of the limited length of time in which the remedē® System has been studied, we are concerned that any claims on mortality as they relate to treatment involving the use of the remedē® System may be limited. Therefore, we are concerned as to whether there is sufficient data to determine that the technology represents a substantial clinical improvement with respect to patients who have been diagnosed with CSA without heart failure.

The applicant has shown that, among the subpopulation of patients who have been diagnosed with CSA and heart failure, the remedē® System decreases morbidity outcomes as compared to the CPAP and ASV treatment options. We understand that not all patients evaluated in the applicant's supporting clinical trials had been diagnosed with CSA with a comorbidity of heart failure. However, in all of the supporting studies for this application, the vast majority of study patients did have this specific comorbidity of CSA and heart failure. Of the three studies which enrolled both patients diagnosed with CSA with and without heart failure,[143] [144] [145] [146] only two studies

[141] Ibid.

[142] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[143] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[144] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T., ''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lancet,* 2016, vol. 388, pp. 974–982.

[145] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

Continued

performed analyses controlling for heart failure status.[147] [148] The data from these two studies, the Costanzo, et al. (2016) and the Respicardia, Inc. executive report, are analyses based on the same pivotal trial data and, therefore, do not provide results from two separate samples. Descriptive comparisons are made in the executive summary of the pivotal trial [149] between all treated and control patients. However, we are unable to determine the similarities and differences between patients with heart failure and non-heart failure treated versus controlled groups. Because randomization resulted in one difference between the overall treated and control groups (MAI events per hour), it is possible that further failures of randomization may have occurred when controlling for heart failure status in unmeasured variables. Finally, the sample size analyzed and the subsample sizes of the heart failure patients (80) and non-heart failure patients (51) are particularly small. It is possible that these results are not representative of the larger population of patients who have been diagnosed with CSA.

Therefore, we are concerned that differences in morbidity and mortality outcomes between CPAP, ASV, and the remedē® System in the general CSA patient population have not adequately been tested or compared. Specifically, the two patient populations, those who have been diagnosed with heart failure and CSA versus those who have been diagnosed with CSA alone, may experience different symptoms and outcomes associated with their disease processes. Patients who have been diagnosed with CSA alone present with excessive sleepiness, poor sleep quality, insomnia, poor concentration, and inattention.[150] Conversely, patients who have been diagnosed with the comorbid conditions of CSA as a result of heart failure experience significant cardiovascular insults resulting from sympathetic nervous system activation, pulmonary hypertension, and arrhythmias, which ultimately contribute to the downward cycle of heart failure.[151]

We also note that the clinical study had a small patient population (n=151), with follow-up for 6 months. We are interested in longer follow-up data that would further validate the points made by the applicant regarding the beneficial outcomes seen in patients who have been diagnosed with CSA who have been treated using the remedē® System. We also are interested in additional information regarding the possibility of electrical stimulation of unintended targets and devices combined with the possibility of interference from outside devices. Furthermore, we are unsure with regard to the longevity of the implanted device, batteries, and leads because it appears that the technology is meant to remain in use for the remainder of a patient's life. We are inviting public comments on whether the remedē® System represents a substantial clinical improvement over existing technologies.

We did not receive any public comments in response to the published notice in the **Federal Register** regarding the substantial clinical improvement criterion for the remedē® System or at the New Technology Town Hall Meeting.

f. Titan Spine nanoLOCK® (Titan Spine nanoLOCK® Interbody Device)

Titan Spine submitted an application for new technology add-on payments for the Titan Spine nanoLOCK® Interbody Device (the Titan Spine nanoLOCK®) for FY 2019. (We note that the applicant previously submitted an application for new technology add-on payments for this device for FY 2017.) The Titan Spine nanoLOCK® is a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). One of the key distinguishing features of the device is the surface manufacturing technique and materials, which produce macro, micro, and nano-surface textures. According to the applicant, the combination of surface topographies enables initial implant fixation, mimics an osteoclastic pit for bone growth, and produces the nano-scale features that interface with the integrins on the outside of the cellular membrane. Further, the applicant noted that these features generate better osteogenic and angiogenic responses that enhance bone growth, fusion, and stability. The applicant asserted that the Titan Spine nanoLOCK®'s clinical features also reduce pain, improve recovery time, and produce lower rates of device complications such as debris and inflammation.

On October 27, 2014, the Titan Spine nanoLOCK® received FDA clearance for the use of five lumbar interbody devices and one cervical interbody device: The nanoLOCK® TA—Sterile Packaged Lumbar ALIF Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TAS—Sterile Packaged Lumbar ALIF Stand Alone Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TL—Sterile Packaged Lumbar Lateral Approach Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TO—Sterile Packaged Lumbar Oblique/PLIF Approach Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; the nanoLOCK® TT—Sterile Packaged Lumbar TLIF Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy; and the nanoLOCK® TC—Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy.

The applicant received FDA clearance on December 14, 2015, for the nanoLOCK® TCS— Sterile Package Cervical Stand Alone Interbody Fusion Device with nanoLOCK® surface, available in multiple sizes to accommodate anatomy. According to the applicant, July 8, 2016 was the first date that the nanotechnology production facility completed validations and clearances needed to manufacture the nanoLOCK® interbody fusion devices. Once validations and clearances were completed, the technology was available on the U.S. market on October 1, 2016. Therefore, the applicant believes that the newness period for nanoLOCK® would begin on October 1, 2016. Procedures involving the Titan Spine nanoLOCK® technology can be identified by the following ICD–10–PCS Section ''X'' New Technology codes:

- XRG0092 (Fusion of occipital-cervical joint using nanotextured

[146] Jagielski, D., Ponikowski, P., Augostini, R., Kolodziej, A., Khayat, R., & Abraham, W.T., ''Transvenous Stimulation of the Phrenic Nerve for the Treatment of Central Sleep Apnoea: 12 months' experience with the remede®system,'' *European Journal of Heart Failure,* 2016, pp. 1–8.

[147] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[148] Costanzo, M.R., Ponikowski, P., Javaheri, S., Augostini, R., Goldberg, L., Holcomb, R., Abraham, W.T., ''Transvenous Neurostimulation for Centra Sleep Apnoea: A randomised controlled trial,'' *Lacet,* 2016, vol. 388, pp. 974–982.

[149] Respicardia, Inc. (n.d.). Remede System Pivotal Trial. *https://clinicaltrials.gov/ct2/show/NCT01816776.*

[150] Badr, M.S., 2017, Dec 11, ''Central sleep apnea: Risk factors, clinical presentation, and diagnosis,'' Available at: *https://www.uptodate.com/contents/central-sleep-apnea-risk-factors-clinical-presentation-and-diagnosis?csi=d3a535e6–1cca-4cd5-ab5e-50e9847bda6c&source=contentShare.*

[151] Abraham, W., Jagielski, D., Oldenburg, O., Augostini, R., Kreuger, S., Kolodziej, A., Ponikowski, P., ''Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea,'' *JACC: Heart Failure,* 2015, vol. 3(5), pp. 360–369.

surface interbody fusion device, open approach);
- XRG1092 (Fusion of cervical vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRG2092 (Fusion of 2 or more cervical vertebral joints using nanotextured surface interbody fusion device, open approach);
- XRG4092 (Fusion of cervicothoracic vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRG6092 (Fusion of thoracic vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRG7092 (Fusion of 2 to 7 thoracic vertebral joints using nanotextured surface interbody fusion device, open approach);
- XRG8092 (Fusion of 8 or more thoracic vertebral joints using nanotextured surface interbody fusion device, open approach);
- XRGA092 (Fusion of thoracolumbar vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRGB092 (Fusion of lumbar vertebral joint using nanotextured surface interbody fusion device, open approach);
- XRGC092 (Fusion of 2 or more lumbar vertebral joints using nanotextured surface interbody fusion device, open approach); and
- XRGD092 (Fusion of lumbosacral joint using nanotextured surface interbody fusion device, open approach).

We note that the applicant expressed concern that interbody fusion devices that have failed to gain or apply for FDA clearance with nanoscale features could confuse health care providers with marketing and advertising using terms related to nanotechnology and ultimately adversely affect patient outcomes. Therefore, the applicant believed that there is a need for additional clarity to the current ICD–10–PCS Section ''X'' codes previously identified for health care providers regarding interbody fusion nanotextured surface devices. The applicant submitted a request for code revisions at the March 2018 ICD–10 Coordination and Maintenance Meeting regarding the ICD–10–PCS Section ''X'' New Technology codes used to identify procedures involving the Titan Spine nanoLOCK® technology.

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 the purposes of new technology add-on payments. We note that the substantial similarity discussion is applicable to both the lumbar and the cervical interbody devices because all of the devices use the Titan Spine nanoLOCK® technology.

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 stated that, for both interbody devices (the lumbar and the cervical interbody device), the Titan Spine nanoLOCK®'s surface stimulates osteogenic cellular response to assist in bone formation during fusion. According to the applicant, the mechanism of action exhibited by the Titan Spine's nanoLOCK® surface technology involves the ability to create surface features that are meaningful to cellular regeneration at the nano-scale level. During the manufacturing process, the surface produces macro, micro, and nano-surface textures. The applicant believes that this unique combination and use of these surface topographies represents a new approach to stimulating osteogenic cellular response. The applicant further asserted that the macro-scale textured features are important for initial implant fixation; the micro-scale textured features mimic an osteoclastic pit for supporting bone growth; and the nano-scale textured features interface with the integrins on the outside of the cellular membrane, which generates the osteogenic and angiogenic (mRNA) responses necessary to promote healthy bone growth and fusion. The applicant stated that when correctly manufactured, an interbody fusion device includes a hierarchy of complex surface features, visible at different levels of magnification, that work collectively to impact cellular response through mechanical, cellular, and biochemical properties. The applicant stated that Titan Spine's proprietary and unique surface technology, the Titan Spine nanoLOCK® interbody devices, contain optimized nano-surface characteristics, which generate the distinct cellular responses necessary for improved bone growth, fusion, and stability. The applicant further stated that the Titan Spine nanoLOCK®'s surface engages with the strongest portion of the vertebral endplate, which enables better resistance to subsidence because a unique dual acid-etched titanium surface promotes earlier bone in-growth. According to the applicant, the Titan Spine nanoLOCK®'s surface is created by using a reductive process of the titanium itself. The applicant asserted that use of the Titan Spine nanoLOCK® significantly reduces the potential for debris generated during impaction when compared to treatments using Polyetheretherketone (PEEK)-based implants coated with titanium. According to the results of an *in vitro* study [152] (provided by the applicant), which examined factors produced by human mesenchymal stem cells on spine implant materials that compared angiogenic factor production using PEEK-based versus titanium alloy surfaces, osteogenic production levels were greater with the use of rough titanium alloy surfaces than the levels produced using smooth titanium alloy surfaces. Human mesenchymal stem cells were cultured on tissue culture polystyrene, PEEK, smooth TiAlV, or macro-/micro-/nanotextured rough TiAlV (mmnTiAlV) disks. Osteoblastic differentiation and secreted inflammatory interleukins were assessed after 7 days. The results of an additional study [153] provided by the applicant examined whether inflammatory microenvironment generated by cells as a result of use of titanium aluminum-vanadium (Ti-alloy, TiAlV) surfaces is effected by surface micro-texture, and whether it differs from the effects generated by PEEK-based substrates. This *in vitro* study compared angiogenic factor production and integrin gene expression of human osteoblast-like MG63 cells cultured on PEEK or titanium-aluminum vanadium (titanium alloy). Based on these study results, the applicant asserted that the use of micro-textured surfaces has demonstrated greater promotion of osteoblast differentiation when compared to use of PEEK-based surfaces.

The applicant maintains that the nanoLOCK® was the first, and remains the only, device in spinal fusion, to apply for and successfully obtain a clearance for nanotechnology from the FDA. According to the applicant, in order for a medical device to receive a nanotechnology FDA clearance, the burden of proof includes each of the following to be present on the medical device in question: (1) Proof of specific nano scale features, (2) proof of capability to manufacture nano-scale features with repeatability and documented frequency across an entire

[152] Olivares-Navarrete, R., Hyzy, S., Gittens, R., ''Rough Titanium Alloys Regulate Osteoblast Production of Angiogenic Factors,'' *The Spine Journal,* 2013, vol. 13(11), pp. 1563–1570.

[153] Olivares-Navarrete, R., Hyzy, S., Slosar, P., et al., ''Implant Materials Generate Different Peri-implant Inflammatory Factors,'' SPINE, 2015, vol. 40(6), pp. 339–404.

device, and (3) proof that those nano-scale features provide a scientific benefit, not found on devices where the surface features are not present. The applicant further stated that many of the commercially available interbody fusion devices are created using additive manufacturing processes to mold or build surface from the ground up. Conversely, Titan Spine applied a *subtractive* surface manufacturing to remove pieces of a surface. The surface features that remain after this subtractive process generate features visible at magnifications that additive manufacturing has not been able to produce. According to the applicant, this subtractive process has been validated by the White House Office of Science and Technology, the National Nanotechnology Initiative, and the FDA that provide clearances to products that exhibit unique and repeatable features at predictive frequency due to a manufacturing technique.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, cases representing patients that may be eligible for treatment involving the Titan Spine nanoLOCK® technology would map to the same MS–DRGs as other (lumbar and cervical) interbody devices currently available to Medicare beneficiaries and also are used for the treatment of patients who have been diagnosed with DDD (lumbar or cervical).

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 stated that the Titan Spine nanoLOCK® can be used in the treatment of patients who have been diagnosed with similar types of diseases, such as DDD, and for a similar patient population receiving treatment involving both lumbar and cervical interbody devices.

In summary, the applicant maintained that the Titan Spine nanoLOCK® technology has a different mechanism of action when compared to other spinal fusion devices. Therefore, the applicant did not believe that the Titan Spine nanoLOCK® technology is substantially similar to existing technologies.

We are concerned that the Titan Spine nanoLOCK® interbody devices may be substantially similar to currently available titanium interbody devices because other roughened-surface interbody devices also stimulate bone growth. While there is a uniqueness to the nanotechnology used by the applicant, other devices also stimulate bone growth such as PEEK-based surfaces and, therefore, we remain concerned that the Titan Spine nanoLOCK® interbody devices use the same or similar mechanism of action as other devices.

We are inviting public comments on whether the Titan Spine nanoLOCK® interbody devices are substantially similar to existing technologies and whether these devices meet the newness criterion.

The applicant provided three analyses of claims data from the FY 2016 MedPAR file to demonstrate that the Titan Spine nanoLOCK® interbody devices meet the cost criterion. We note that cases reporting procedures involving lumbar and cervical interbody devices would map to different MS–DRGs. As discussed in the Inpatient New Technology Add-On Payment Final Rule (66 FR 46915), two separate reviews and evaluations of the technologies are necessary in this instance because cases representing patients receiving treatment for diagnoses associated with lumbar procedures that may be eligible for use of the technology under the first indication would not be expected to be assigned to the same MS–DRGs as cases representing patients receiving treatment for diagnoses associated with cervical procedures that may be eligible for use of the technology under the second indication. Specifically, cases representing patients who have been diagnosed with lumbar DDD and who have received treatment that involved implanting a lumbar interbody device would map to MS–DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), MS–DRG 030 (Spinal Procedures without CC/MCC), MS–DRG 453 (Combined Anterior/Posterior Spinal Fusion with MCC), MS–DRG 454 (Combined Anterior/Posterior Spinal Fusion with CC), MS–DRG 455 (Combined Anterior/Posterior Spinal Fusion without CC/MCC), MS–DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC), MS–DRG 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusion without MCC), MS–DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC), MS–DRG 459 (Spinal Fusion Except Cervical with MCC), and MS–DRG 460 (Spinal Fusion Except Cervical without MCC). Cases representing patients who have been diagnosed with cervical DDD and who have received treatment that involved implanting a cervical interbody device would map to MS–DRG 471 (Cervical Spinal Fusion with MCC), MS–DRG 472 (Cervical Spinal Fusion with CC), and MS–DRG 473 (Cervical Spinal Fusion without CC/MCC). Procedures involving the implantation of lumbar and cervical interbody devices are assigned to separate MS–DRGs. Therefore, the devices categorized as lumbar interbody devices and the devices categorized as cervical interbody devices must distinctively (each category) meet the cost criterion and the substantial clinical improvement criterion in order to be eligible for new technology add-on payments beginning in FY 2019.

The first analysis searched for any of the ICD–10–PCS procedure codes within the code series Lumbar—0SG [body parts 0 1 3] [open approach only 0] [device A only] [anterior column only 0, J], which typically are assigned to MS–DRGs 028, 029, 030, and 453 through 460. The average case-weighted unstandardized charge per case was $153,005. The applicant then removed charges related to the predicate technology and then standardized the charges. The applicant then applied an inflation factor of 1.09357, the value used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to update the charges from FY 2016 to FY 2018. The applicant added charges related to the Titan Spine nanoLOCK® lumbar interbody devices. This resulted in a final inflated average case-weighted standardized charge per case of $174,688, which exceeds the average case-weighted Table 10 MS–DRG threshold amount of $83,543.

The second analysis searched for any of the ICD–10–PCS procedure codes within the code series Cervical—0RG [body parts 0—A] [open approach only 0] [device A only] [anterior column only 0, J], which typically are assigned to MS–DRGs 028, 029, 030, 453 through 455, and 471 through 473. The average case-weighted unstandardized charge per case was $88,034. The methodology used in the first analysis was used for the second analysis, which resulted in a final inflated average case-weighted standardized charge per case of $101,953, which exceeds the average case-weighted Table 10 MS–DRG threshold amount of $83,543.

The third analysis was a combination of the first and second analyses described earlier that searched for any of the ICD–10–PCS procedure codes within the Lumbar and Cervical code series listed above that are assigned to the MS–DRGs in the analyses above. The average case-weighted unstandardized charge per case was $127,736. The methodology used for the first and second analysis was used for the third analysis, which resulted in a

final inflated average case-weighted standardized charge per case of $149,915, which exceeds the average case-weighted Table 10 MS–DRG threshold amount of $104,094.

Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount in all of the applicant's analyses, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the Titan Spine nanoLOCK® meets the cost criterion.

With regard to the substantial clinical improvement criterion for the Titan Spine nanoLOCK® Interbody Lumbar and Cervical Devices, the applicant submitted the results of two clinical evaluations. The first clinical evaluation was a case series and the second was a case control study. Regarding the case series, 4 physicians submitted clinical information on 146 patients. The 146 patients resulted from 2 surgery groups: a cervical group of 73 patients and a lumbar group of 73 patients. The division into cervical and lumbar groups was due to differences in surgical procedure and expected recovery time. Subsequently, the collection and analyses of data were presented for lumbar and cervical nanoLOCK® device implants. Data was collected using medical record review. Patient baseline characteristics, the reason for cervical and lumbar surgical intervention, inclusion and exclusion criteria, details on the types of pain medications and the pattern of usage preoperatively and postoperatively were not provided. We note that the applicant did not provide an explanation of why the outcomes studied in the case series were chosen for review. However, the applicant noted that the case series data were restricted to patients treated with the Titan Spine nanoLOCK® device, with both retrospective and prospective data collection. These data appeared to be clinically related and included: (1) Pain medication usage; (2) extremity and back pain (assessed using the Numeric Pain Rating Scale (NPRS)); and (3) function (assessed using the Oswestry Disability Index (ODI)). Clinical data collection began with time points defined as ''Baseline (pre-operation), Month 1 (0–4 weeks), Month 2 (5–8 weeks), Month 3 (9–12 weeks), Month 4 (13–16 weeks), Month 5 (17–20 weeks) and Month 6+ (>20 weeks)''. The *n,* mean, and standard deviation were presented for continuous variables (NPRS extremity pain, back pain, and ODI scores), and the *n* and percentage were presented for categorical variables (subjects taking pain medications). All analyses compared the time point (for example, Month 1) to the baseline.

Pain scores for extremities (leg and arm) were assessed using the NPRS, an 11-category ordinal scale where 0 is the lowest value and 10 is the highest value and, therefore, higher scores indicate more severe pain. Of the 73 patients in the lumbar group, the applicant presented data on 18 cases for leg or arm pain at baseline that had a mean score of 6.4, standard deviation (SD) 2.3. Between Month 1 and Month 6+ the number of lumbar patients for which data was submitted for leg or arm pain ranged from 3 patients (Month 5, mean score 3.7, SD 3.5) to 15 patients (Month 6+, mean score 2.5, SD 2.4), with varying numbers of patients for each of the other defined time points of Month 1 through Month 4. None of the defined time points of Month 1 through Month 4 had more than 14 patients or less than 3 patients that were assessed.

Of the 73 patients in the cervical group, 7 were assessed for leg or arm pain at baseline and had a mean score of 5.1, SD 3.5. Between Month 1 and Month 6+ the number of cervical patients assessed for leg or arm pain ranged from 0 patients (Month 5, no scores) to 5 patients (Month 1, mean score 4.2, SD 2.6), with varying numbers of patients for each of the other defined time points of Month 1 through Month 4. None of the defined time points of Month 1 through Month 4 had more than 5 patients or less than 2 patients that were assessed.

Back pain scores were also assessed using the NPRS, where 0 is the lowest value and 10 is the highest value and, therefore, higher scores indicate more severe pain. Of the 73 patients in the lumbar group, 66 were assessed for back pain at baseline and had a mean score of 7.9, SD 1.8. Between Month 1 and Month 6+ the number of lumbar patients assessed for back pain ranged from 4 patients (Month 5, mean score 4.0, SD 2.7) to 43 patients (Month 1, mean score 4.5, SD 2.7), with varying numbers of patients for each defined time point.

Of the 73 patients in the cervical group, 71 were assessed for back pain at baseline and had a mean score of 7.5, SD 2.3. Between Month 1 and Month 6+ the number of cervical patients assessed for back pain ranged from 2 patients (Month 5, mean score 7.0, SD 2.8) to 47 patients (Month 1, mean score 4.4, SD 2.9), with varying numbers of patients for each defined time point.

Function was assessed using the ODI, which ranges from 0 to 100, with higher scores indicating increased disability/impairment. Of the 73 patients in the lumbar group, 59 were assessed for ODI scores at baseline and had a mean score of 52.5, SD 18.7. Between Month 1 and Month 6+ the number of lumbar patients assessed for ODI scores ranged from 3 patients (Month 5, mean score 33.3, SD 19.8) to 38 patients (Month 1, mean score 48.1, SD 19.7), with varying numbers of patients for each defined time point. Of the 73 patients in the cervical group, 56 were assessed for ODI scores at baseline and had a mean score of 53.6, SD 18.2. Between Month 1 and Month 6+ the number of cervical patients assessed for ODI score ranged from 1 patient (Month 5, mean score 80, no SD noted) to 41 patients (Month 1, mean score 48.6, SD 20.5), with varying numbers of patients for each defined time point.

The percentages of patients not taking pain medicines per day for the lumbar and cervical groups over time were assessed. Of the 73 patients in the lumbar group, 69 were assessed at baseline and 27.5 percent of the 69 patients were not taking pain medication. Between Month 1 and Month 6+ the number of lumbar patients assessed for not taking pain medicines ranged from 5 patients (Month 5, 80 percent were not taking pain medicines) to 46 patients (Month 1, 54.3 percent were not taking pain medicines), with varying numbers of patients for each defined time point. Of the 73 patients in the cervical group, 72 were assessed and 22.2 percent of the 72 patients were not taking pain medicines at baseline. Between Month 1 and Month 6+ the number of cervical patients assessed for not taking pain medicines ranged from 2 patients (Month 5, 100 percent were not taking pain medicines) to 50 patients (Month 1, 70 percent were not taking pain medicines), with varying numbers of patients for each defined time point.

According to the applicant, both the lumbar and cervical groups showed a trend of improvement in all four clinical outcomes over time for which they collected data in their case series. However, the applicant also indicated that the trend was difficult to assess due to the relatively limited number of subjects with available assessments more than 4 months post-implant. The applicant shared that it had missing values for over 80 percent of the subjects in the study after the 4th post-operative month. According to the applicant and its results of the clinical evaluation, which was based on data from less than 20 percent of subjects, there was a statistically significant reduction in back pain for nanoLOCK® patients from ''Baseline,'' based on improvement at earlier than standard time points.

We are concerned that the small sample size of patients assessed at each timed follow-up point for each of the clinical outcomes evaluated in the case series limits our ability to draw meaningful conclusions from these results. The applicant provided t-test results for the lumbar and cervical groups assessed for pain (back, leg, and arm). We are concerned that the t-test resulting from small sample sizes (for example, 2 of 73 patients in Month 5, and 5 of 73 patients in Month 6+) does not indicate a statistically meaningful improvement in pain scores.

Based on the results of the case series provided by the applicant, we are unable to determine whether the findings regarding extremity and back pain, ODI scores, and percentage of subjects not taking pain medication for patients who received treatment involving the Titan Spine nanoLOCK® devices represent a substantial clinical improvement due to the inconsistent sample size over time across both treatment arms in all evaluated outcome measures. The quantity of missing data in this case series, along with the lack of explanation for the missing data, raises concerns for the interpretation of these results. We also are unable to determine based on this case series whether there were improvements in extremity pain and back pain, ODI scores, and percentage of subjects not taking pain medicines for patients who received treatment involving the Titan Spine nanoLOCK® devices versus conventional and other intervertebral body fusion devices, as there were no comparisons to current therapies. As noted above, the applicant did not provide an explanation of why the outcomes studied in the case series were chosen for review. Therefore, we believe that we may have insufficient information to determine if the outcomes studied in the case series are validated proxies for evidence that the nanoLOCK®'s surface promotes greater osteoblast differentiation when compared to use of PEEK-based surfaces. We are inviting public comments regarding our concerns, including with respect to why the outcomes studied in the case series were chosen for review.

The applicant's second clinical evaluation was a case-control study with a 1:5 case control ratio. The applicant used deterministically linked, de-identified, individual-level health care claims, electronic medical records (EMR), and other data sources to identify 70 cases and 350 controls for a total sample size of 420 patients. The applicant also identified OM1™ data source and noted that the OM1™ data source reflects data from all U.S. States and territories and is representative of the U.S. national population. The applicant used OM1™ data between January 2016 and June 2017, and specifically indicated that these data contain medical and pharmacy claims information, laboratory data, vital signs, problem lists, and other clinical details. The applicant indicated that cases were selected using the ICD–10–PCS Section ''X'' New Technology codes listed above and controls were chosen from fusion spine procedures (Fusion Spine Anterior Cervical, Fusion Spine Anterior Cervical and Discectomy, Fusion Spine Anterior Posterior Cervical, Fusion Spine Transforaminal Interbody Lumbar, Fusion Spine Cervical Thoracic, Fusion Spine Transforaminal Interbody Lumbar with Navigation, and Fusion Spine Transforaminal Interbody Lumber Robot-Assisted). Further, the applicant stated that cases and controls were matched by age (within 5 years), year of surgery, Charlson Comorbidity Index, and gender. According to the applicant, regarding clinical outcomes studied, unlike the case series, the case-control study captured Charlson Comorbidity Index, the average length of stay (ALOS), and 30-day unplanned readmissions; like the case series, this case-control study captured the use of pain medications by assessing the cumulative post-surgical opioid use.

The mean age for all patients in the study was 55 years old, and 47 percent were male. For the clinical length of stay outcome, the applicant noted that the mean length of stay was slightly longer among control patients, 3.9 days (SD = 5.4) versus 3.2 days (SD = 2.9) for cases, and a larger proportion of patients in the control group had lengths of stay equal to or longer than 5 days (21 percent versus 17 percent). Three control patients (0.8 percent) were readmitted within 30 days compared to zero readmissions among case patients. A slightly lower proportion of case patients were on opioids 3 months post-surgery compared to control patients (15 percent versus 16 percent).

We are concerned that there may be significant outliers not identified in the case and control arms because for the mean length of stay outcome, the standard deviation for control patients (5.4 days) is larger than the point estimate (3.9 days). Based on the results of this clinical evaluation provided by the applicant, we are unable to determine whether the findings regarding lengths of stay and cumulative post-surgical opioid use for patients who received treatment involving the nanoLOCK® devices versus conventional intervertebral body fusion devices represent a substantial clinical improvement. Without further information on selection of controls and whether there were adjustments in the statistical analyses controlling for confounding factors (for example, cause of back pain, level of experience of the surgeon, BMI and length of pain), we are concerned that the interpretation of the results may be limited. Finally, we are concerned that the current data does not adequately support a strong association between the outcome measures of length of stay, readmission rates, and use of opioids and the use of nano-surface textures in the manufacturing of the Titan Spine nanoLOCK® device. For these reasons, we are concerned that the current data do not support a substantial clinical improvement over the currently available devices used for lumbar and cervical DDD treatment.

We note that the applicant indicated its intent to submit the results of additional ongoing studies to support the evidence of substantial clinical improvement over existing technologies for patients who receive treatment involving the nanoLOCK® devices versus patients receiving treatment involving other interbody fusion devices. We are inviting public comments on whether the Titan Spine nanoLOCK® meets the substantial clinical improvement criterion.

Below we summarize and respond to written public comments received regarding the nanoLOCK® during the open comment period in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: One commenter focused on two items related to the substantial clinical improvement and the lack of real-world evidence and published studies regarding the nanoLOCK® technologies. The first item referenced by the commenter related to CMS' concern presented in the FY 2017 IPPS/LTCH PPS final rule that the results of the *in vitro* studies that the applicant for the nanoLOCK® technology relied upon in its application may not have necessarily correlated with the clinical results specified by the applicant. Specifically, because at that time the applicant had only conducted *in vitro* studies, without obtaining any clinical data from live patients during a specific clinical trial, CMS stated that it was unable to substantiate the clinical results that the applicant believed the technology achieved from a clinical standpoint based on the results of the studies provided. As a result, CMS stated that it was concerned that the results of the studies provided by the

applicant did not demonstrate that the Titan Spine nanoLOCK® technologies met the substantial clinical improvement criterion. The commenter also indicated that it believed the applicant has yet to publish data that would satisfy the concerns CMS noted in the FY 2017 IPPS/LTCH PPS final rule. In addition, the commenter noted that the applicant suggested that the health care community has started to move away from randomized controlled trials toward real-world evidence, and then presented claims analyses that attempted to link any assumed substantial clinical improvement in patient outcomes from fusion surgery to the nanoLOCK® technology. In response to this assertion, the commenter stated that without a randomized controlled study of this technology as compared to the standard of care or, as CMS noted in FY 2017, clinical data from live patients during a specific clinical trial, these links cannot be scientifically substantiated. The commenter also noted that none of the studies presented during the February 13, 2018 New Technology Town Hall meeting appear to be published at this time, which would subject them to a rigorous peer-reviewed process. The commenter continued to support CMS' concern previously expressed in the FY 2017 IPPS/LTCH PPS final rule regarding whether substantial clinical improvement has been demonstrated.

The second item of focus referenced by the commenter was also presented by CMS in the FY 2017 IPPS/LTCH PPS final rule. The commenter noted that there are other titanium surfaced devices currently available on the U.S. market. In the FY 2017 IPPS/LTCH PPS final rule, CMS stated that, while these devices do not use the Titan Spine nanoLOCK® technology, their surfaces also are made of titanium. Therefore, CMS believed that the Titan Spine nanoLOCK® interbody devices may be substantially similar to currently available titanium interbody devices. The commenter stated that it agreed with the statements CMS made in the FY 2017 IPPS/LTCH PPS final rule and also believed that the Titan Spine nanoLOCK® technology is not only substantially similar to other currently available titanium interbody devices, but also is similar to other technologies with microscopic, roughened surfaces with nano-scale features. The commenter indicated that the verification of these surfaces and visualization of nano-scale features in other orthopedic and spinal implants have been confirmed in consensus standards, as well as in electron microscopy techniques, including atomic force microscopy. In addition, the commenter stated that the success of these devices at an *in vitro* level has been reported in the peer-reviewed literature, similar to that published on the nanoLOCK®. Despite verification of the applicant's claims regarding these surfaces, visualization of nano-scale features, and success of these devices at an *in vitro* level being reported in peer-reviewed literature, the commenter believed that, at this time, there is not enough scientifically-validated evidence of improvement in patient outcomes to substantiate approval of new technology add-on payments for any device manufactured with nano-scale features, including the Titan Spine nanoLOCK® technology.

Response: We appreciate the commenter's input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for the Titan Spine nanoLock® for FY 2019.

Comment: One commenter supported the approval of new technology add-on payments for the Titan Spine nanoLock® technology. The commenter stated that Titan Spine is the only company that has received FDA approval for the use of ''nanotechnology'' in its indication for treatment use and has published substantial research on the cellular impact of its unique topographic, nano-textured surface. (We note, as described above, this technology is currently FDA cleared (not FDA approved) and the technology was available on the U.S. market once validations and clearances were completed.) The commenter asserted that, for these reasons, the nanoLOCK® represents an emerging technology that should not be considered substantially similar to other spinal technologies on the market. The commenter further asserted that the real-world evidence gathered from multiple, independent data sources (including actual electronic medical records (EMR) and healthcare claims) on nanoLOCK® usage in the treatment of patients consistently shows patient improvement in terms of clinically and economically relevant outcomes—faster recovery times, reduced length of hospital stays, and reductions in downstream medical costs such as opiate utilization, among others. The commenter stated that impressive patient outcomes by use of the nanoLOCK® are unmatched by other competing devices, improving patient outcomes of Medicare beneficiaries with serious spinal pathologies.

Response: We appreciate the commenters' input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for the Titan Spine nanoLock® for FY 2019.

g. Plazomicin

Achaogen, Inc. submitted an application for new technology add-on payments for Plazomicin for FY 2019. According to the applicant, Plazomicin is a next-generation aminoglycoside antibiotic, which has been found in vitro to have enhanced activity against many multi-drug resistant (MDR) gram-negative bacteria. The proposed indication for the use of Plazomicin, which had not received FDA approval as of the time of the development of this proposed rule, is for the treatment of adult patients who have been diagnosed with the following infections caused by designated susceptible microorganisms: (1) Complicated urinary tract infection (cUTI), including pyelonephritis; and (2) bloodstream infections (BSIs). The applicant stated that it expects that Plazomicin would be reserved for use in the treatment of patients who have been diagnosed with these types of infections who have limited or no alternative treatment options, and would be used only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms.

The applicant stated that there is a strong need for antibiotics that can treat infections caused by MDR Enterobacteriaceae, specifically carbapenem resistant Enterobacteriaceae (CRE). Life-threatening infections caused by MDR bacteria have increased over the past decade, and the patient population diagnosed with infections caused by CRE is projected to double within the next 5 years, according to the Centers for Disease Control and Prevention (CDC). Infections caused by CRE are often associated with poor patient outcomes due to limited treatment options. Patients who have been diagnosed with BSIs due to CRE face mortality rates of up to 50 percent. Patients most at risk for CRE infections are those with CRE colonization, recent hospitalization or stay in a long-term care or skilled-nursing facility, an extensive history of antibacterial use, and whose care requires invasive devices like urinary catheters, intravenous (IV) catheters, or ventilators. The applicant estimated, using data from the Center for Disease Dynamics, Economics & Policy (CDDEP), that the Medicare population that has been diagnosed with antibiotic-resistant cUTI numbers approximately 207,000 and approximately 7,000 for BSIs/sepsis due to CRE.

The applicant noted that due to the public health concern of increasing antibiotic resistance and the need for new antibiotics to effectively treat MDR infections, Plazomicin has received the following FDA designations: Breakthrough Therapy; Qualified Infectious Disease product, Priority Review; and Fast Track. The applicant noted that Breakthrough Therapy designation was granted on May 17, 2017, for the treatment of bloodstream infections (BSIs) caused by certain Enterobacteriaceae in patients who have been diagnosed with these types of infections who have limited or no alternative treatment options. The applicant noted that Plazomicin is the first antibacterial agent to receive this designation. The applicant noted that on December 18, 2014, the FDA designated Plazomicin as a Qualified Infectious Disease Product (QIDP) for the indications of hospital-acquired bacterial pneumonia (HAPB), ventilator-associated bacterial pneumonia (VABP), and complicated urinary tract infection (cUTI), including pyelonephritis and catheter-related blood stream infections (CRBSI). The applicant noted that Fast Track designation was granted by the FDA on August 12, 2012, for the Plazomicin development program for the treatment of serious and life-threatening infections due to CRE. Plazomicin had not received approval from the FDA as of the time of the development of this proposed rule. However, the applicant indicated that it anticipates receiving approval from the FDA by July 1, 2018. The applicant has submitted a request for approval for a unique ICD–10–PCS procedure code for the use of Plazomicin, beginning with FY 2019.

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 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 Plazomicin does not use the same or similar mechanism of action to achieve a therapeutic outcome as any other drug assigned to the same or a different MS–DRG. The applicant stated that Plazomicin has a unique chemical structure designed to improve activity against aminoglycoside-resistant bacteria, which also are often resistant to other key classes of antibiotics, including beta-lactams and carbapenems. Bacterial resistance to aminoglycosides usually occurs through enzymatic modification by aminoglycoside modifying enzymes (AMEs) to compromise binding the target bacterial site. According to the applicant, AMEs were found in 98.6 percent of aminoglycoside nonsusceptible E. coli, Klebsiella spp, Enterobacter spp, and Proteus spp collected in 2016 U.S. surveillance studies. Genes encoding AMEs are typically located on elements that also carry other causes of antibiotic resistance like B-lactamase and/or carbapenemase genes. Therefore, extended spectrum beta-lactamases (ESBL) producing Enterobacteriaceae and CRE are commonly resistant to currently available aminoglycosides. According to the applicant, Plazomicin contains unique structural modifications at key positions in the molecule to overcome antibiotic resistance, specifically at the 6 and N1 positions. These side chain substituents shield Plazomicin from inactivation by AMEs, such that Plazomicin is not inactivated by any known AMEs, with the exception of N-acetyltransferase (AAC) 2'-Ia, -Ib, and -Ic, which is only found in Providencia species. According to the applicant, as an aminoglycoside, Plazomicin also is not hydrolyzed by B-lactamase enzymes like ESBLs and carbapenamases. Therefore, the applicant asserted that Plazomicin is a potent therapeutic agent for treating MDR Enterobacteriaceae, including aminoglycoside-resistant isolates, CRE strains, and ESBL-producers.

The applicant asserted that the mechanism of action is new due to the unique chemical structure. With regard to the general mechanism of action against bacteria, we are concerned that the mechanism of action of Plazomicin appears to be similar to other aminoglycoside antibiotics. As with other aminoglycosides, Plazomicin is bactericidal through inhibition of bacterial protein synthesis. The applicant maintained that the structural changes to the antibiotic constitute a new mechanism of action because it allows the antibiotic to remain active despite AMEs. Additionally, the applicant stated that Plazomicin would be the first, new aminoglycoside brought to market in over 40 years.

We are inviting public comments on whether Plazomicin's mechanism of action is new, including comments in response to our concern that its mechanism of action to eradicate bacteria (inhibition of bacterial protein synthesis) may be similar to that of other aminoglycosides, even if improvements to its structure may allow Plazomicin to be active even in the presence of common AMEs that inactivate currently marketed aminoglycosides.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we believe that potential cases representing patients who may be eligible for treatment involving Plazomicin would be assigned to the same MS–DRGs as cases representing patients who receive treatment for UTI or bacteremia.

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 asserted that Plazomicin is intended for use in the treatment of patients who have been diagnosed with cUTI, including pyelonephritis, and bloodstream infections, who have limited or no alternative treatment options. Because the applicant anticipates that Plazomicin will be reserved for use in the treatment of patients who have limited or no alternative treatment options, the applicant believed that Plazomicin may be indicated to treat a new patient population for which no other technologies are available. However, it is possible that existing antimicrobials could also be used to treat those same bacteria Plazomicin is intended to treat. Specifically, the applicant is seeking FDA approval for use in the treatment of patients who have been diagnosed with cUTI, including pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli* (including cases with concurrent bacteremia), *Klebsiella pneumoniae, Proteus* spp (including *P. mirabilis* and *P. vulgaris*), and *Enterobactercloacae,* and for use in the treatment of patients who have been diagnosed with BSIs caused by the following susceptible microorganisms: *Klebsiella pneumonia* and *Escherichia coli.* Because the susceptible organisms for which Plazomicin is proposed to be indicated include nonresistant strains that existing antibiotics may effectively treat, we are concerned that Plazomicin may not treat a new patient population. Therefore, we are inviting public comments on whether Plazomicin treats a new type of disease or a new patient population. We also are inviting public comments on whether Plazomicin is substantially similar to any 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. In order to identify the range of MS–DRGs that potential cases representing

patients who have been diagnosed with the specific types of infections for which the technology has been proposed to be indicated for use in the treatment of and who may be potentially eligible for treatment involving Plazomicin may map to, the applicant identified all MS–DRGs in claims that included cases representing patients who have been diagnosed with UTI or Septicemia. The applicant searched the FY 2016 MedPAR data for claims reporting 16 ICD–10–CM diagnosis codes for UTI and 45 ICD–10–CM diagnosis codes for Septicemia and identified a total of 2,046,275 cases assigned to 702 MS–DRGs. The applicant also performed a similar analysis based on 75 percent of identified claims, which spanned 43 MS–DRGs. MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC) accounted for roughly 25 percent of all cases in the first analysis of the 702 MS–DRGs identified, and almost 35 percent of the cases in the second analysis of the 43 MS–DRGs identified. Other MS–DRGs with a high volume of cases based on mapping the ICD–10–CM diagnosis codes, in order of number of discharges, were: MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC); MS–DRG 690 (Kidney and Urinary Tract Infections without MCC); MS–DRG 689 (Kidney and Urinary Tract Infections with MCC); MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC); and MS–DRG 683 (Renal Failure with CC).

The applicant calculated an average unstandardized case-weighted charge per case using 2,046,275 identified cases (100 percent of all cases) and using 1,533,449 identified cases (75 percent of all cases) of $69,414 and $63,126, respectively. The applicant removed 50 percent of the charges associated with other drugs (associated with revenue codes 025x, 026x, and 063x) from the MedPAR data because the applicant anticipates that the use of Plazomicin would reduce the charges associated with the use of some of the other drugs, noting that this was a conservative estimate because other drugs would still be required for these patients during their hospital stay. The applicant then standardized the charges and applied the 2-year inflation factor of 9.357 percent from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527) to inflate the charges from FY 2016 to FY 2018. No charges for Plazomicin were added in the analysis because the applicant explained that the anticipated price for Plazomicin has yet to be determined. Based on the FY 2018 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $56,996 in the first scenario utilizing 100 percent of all cases, and $55,363 in the second scenario utilizing 75 percent of all cases. The inflated average case-weighted standardized charge per case was $62,511 in the first scenario and $57,054 in the second analysis. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount in both scenarios, the applicant maintained that the technology meets the cost criterion. The applicant noted that the case-weighted threshold amount is met before including the average per patient cost of the technology in both analyses. As such, the applicant anticipated that the inclusion of the cost of Plazomicin, at any price point, would further increase charges above the average case-weighted threshold amount.

The applicant also supplied additional cost analyses, directing attention at each of the two proposed indications individually; the cost analyses considered potential cases representing patients who have been diagnosed with cUTI who may be eligible for treatment involving Plazomicin separately from potential cases representing patients who have been diagnosed with BSI/Bacteremia who may be eligible for treatment involving Plazomicin, with the cost analysis for each considering 100 percent and 75 percent of identified cases using the FY 2016 MedPAR data and the FY 2018 GROUPER Version 36. The applicant reported that, for potential cases representing patients who have been diagnosed with Bacteremia and who may be eligible for treatment involving Plazomicin, 100 percent of identified cases spanned 539 MS–DRGs, with 75 percent of the cases mapping to the following 4 MS–DRGs: 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC), 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC), 853 (Infectious and Parasitic Diseases with O.R. Procedure with MCC), and 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ hours).

According to the applicant, for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin, 100 percent of identified cases mapped to 702 MS–DRGs, with 75 percent of the cases mapping to 56 MS–DRGs. Potential cases representing patients who have been diagnosed with cUTIs and who may be eligible for treatment involving Plazomicin assigned to MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC) accounted for approximately 18 percent of all of the cases assigned to any of the identified 56 MS–DRGs (75 percent of cases sensitivity analysis), followed by MS–DRG 690 (Kidney and Urinary Tract Infections without MCC), which comprised almost 13 percent of all of the cases assigned to any of the identified 56 MS–DRGs. Two other common MS–DRGs containing potential cases representing potential patients who may be eligible for treatment involving Plazomicin who have been diagnosed with the specific type of indicated infections for which the technology is intended to be used, using the applicant's analysis approach for UTI based on mapping the ICD–10–CM diagnosis codes were: MS–DRG 872 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours without MCC) and MS–DRG 689 (Kidney and Urinary Tract Infections with MCC).

For potential cases representing patients who have been diagnosed with BSI and who may be eligible for treatment involving Plazomicin, the applicant calculated the average unstandardized case-weighted charge per case using 1,013,597 identified cases (100 percent of all cases) and using 760,332 identified cases (75 percent of all cases) of $87,144 and $67,648, respectively. The applicant applied the same methodology as the combined analysis above. Based on the FY 2018 IPPS/LTCH PPS final rule Table 10 thresholds, the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI assigned to the MS–DRGs identified in the sensitivity analysis was $66,568 in the first scenario utilizing 100 percent of all cases, and $61,087 in the second scenario utilizing 75 percent of all cases. The inflated average case-weighted standardized charge per case was $77,004 in the first scenario and $60,758 in the second scenario; in the 100 percent of Bacteremia cases sensitivity analysis, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the sensitivity analysis by $10,436 before including costs of Plazomicin. In the 75 percent of all cases sensitivity analysis scenario, the

final inflated case-weighted standardized charge per case did not exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI assigned to the MS–DRGs identified in the sensitivity analysis, at $329 less than the average case-weighted threshold amount. Because the applicant has not yet determined pricing for Plazomicin, however, it is possible that Plazomicin may also exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with BSI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent cases sensitivity analysis.

For potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin, the applicant calculated the average unstandardized case-weighted charge per case using 100 percent of all cases and 75 percent of all cases of $59,908 and $48,907, respectively. The applicant applied the same methodology as the combined analysis above. Based on the FY 2018 IPPS/LTCH PPS final rule Table 10 thresholds, the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the first scenario utilizing 100 percent of all cases was $51,308, and $46,252 in the second scenario utilizing 75 percent of all cases. The inflated average case-weighted standardized charge per case was $53,868 in the first scenario and $45,185 in the second scenario. In the 100 percent of cUTI cases sensitivity analysis, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 100 percent of all cases sensitivity analysis by $2,560 before including costs of Plazomicin. In the 75 percent of all cases scenario, the final inflated case-weighted standardized charge per case did not exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent sensitivity analysis, at $1,067 less than the average case-weighted threshold amount. Because the applicant has not yet determined pricing for Plazomicin, however, it is possible that Plazomicin may also exceed the average case-weighted threshold amount for potential cases representing patients who have been diagnosed with cUTI and who may be eligible for treatment involving Plazomicin assigned to the MS–DRGs identified in the 75 percent of all cases sensitivity analysis if charges for Plazomicin are more than $1,067. We are inviting public comments on whether Plazomicin meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Plazomicin is a next generation aminoglycoside that offers a treatment option for a patient population who have limited or no alternative treatment options. Patients who have been diagnosed with BSI or cUTI caused by MDR Enterobacteria, particularly CRE, are difficult to treat because carbapenem resistance is often accompanied by resistance to additional antibiotic classes. For example, CRE may be extensively drug resistant (XDR) or even pandrug resistant (PDR). CRE are resistant to most antibiotics, and sometimes the only treatment option available to health care providers is a last-line antibiotic (such as colistin and tigecycline) with higher toxicity. According to the applicant, Plazomicin would give the clinician an alternative treatment option for patients who have been diagnosed with MDR bacteria like CRE because it has demonstrated activity against clinical isolates that possess a broad range of resistance mechanisms, including ESBLs, carbapenemases, and aminoglycoside modifying enzymes that limit the utility of different classes of antibiotics. Plazomicin also can be used to treat patients who have been diagnosed with BSI caused by resistant pathogens, such as ESBL-producing Enterobacteriaceae, CRE, and aminoglycoside-resistant Enterobacteriaceae. The applicant maintained that Plazomicin is a substantial clinical improvement because it offers a treatment option for patients who have been diagnosed with serious bacterial infections that are resistant to current antibiotics. We note that Plazomicin is not indicated exclusively for resistant bacteria, but rather for certain susceptible organisms of gram-negative bacteria, including resistant and nonresistant strains for which existing antibiotics may be effective. We are concerned that the applicant focused solely on Plazomicin's activity for resistant bacteria and did not supply information demonstrating substantial clinical improvement in treating nonresistant strains in the bacteria families for which Plazomicin is indicated.

The applicant stated that Plazomicin also meets the substantial clinical improvement criterion because it significantly improves clinical outcomes for a patient population compared to currently available treatment options. Specifically, the applicant asserted that Plazomicin has: (1) A mortality benefit and improved safety profile in treating patients who have been diagnosed with BSI due to CRE; and (2) statistically better outcomes at test-of-cure in patients who have been diagnosed with cUTI, including higher eradication rates for ESBL-producing pathogens, and lower rate of subsequent clinical relapses. The applicant conducted two Phase III studies, CARE and EPIC. The CARE trial compared Plazomicin to colistin, a last-line antibiotic that is a standard of care agent for patients who have been diagnosed with BSI when caused by CRE. The EPIC trial compared Plazomicin to meropenem for the treatment of patients who have been diagnosed with cUTI/acute polynephritis.

The CARE clinical trial was a randomized, open label, multi-center Phase III study comparing the efficacy of Plazomicin against colistin in the treatment of patients who have been diagnosed with BSIs or hospital-acquired bacterial pneumonia (HABP)/ventilator-acquired bacterial pneumonia (VABP) due to CRE. Due to the small number of enrolled patients with HAPB/VABP, however, results were only analyzed for patients who had been diagnosed with BSI due to CRE. The primary endpoint was day 28 all-cause mortality or significant disease complications. Patients were randomized to receive 7 to 14 days of IV Plazomicin or colistin, along with an adjunctive therapy of meropenem or tigecycline. All-cause mortality and significant disease complications were consistent regardless of adjunctive antibiotics received, suggesting that the difference in outcomes was driven by Plazomicin and colistin, with little impact from meropenem and tigecycline. Follow-up was done at test-of-cure (TOC; 7 days after last dose of IV study drug), end of study (EOS; day 28), and long-term follow-up (LFU; day 60). Safety analysis included all patients; microbiological modified intent-to-treat (mMITT) analysis included 17/18 Plazomicin and 20/21 colisitin patients. Baseline characteristics like age, gender, APACHE II score, infection type,

baseline pathogens, creatinine clearance, and adjunctive therapy with either meropenem or tigecycline were comparable in the Plazomicin and colistin groups.

According to the applicant, the following results demonstrate a reduced mortality benefit in the patients who had been diagnosed with BSI subset. All-cause mortality at day 28 in the Plazomicin group was more than 5 times less than in the colistin group and all-cause mortality or significant complications at day 28 was reduced by 39 percent in the Plazomicin group compared to the colistin group. There was a large sustained 60-day survival benefit in the patients who had been diagnosed with BSI subset, with survival approximately 70 percent in the Plazomicin group compared to 40 percent in the colistin group. Additionally, according to the applicant, faster median time to clearance of CRE bacteremia of 1.5 versus 6 days for Plazomicin versus colistin and higher rate of documented clearance by day 5 (86 percent versus 46 percent) supported the reduced mortality benefit due to faster and more sustained clearance of bacteremia and also demonstrated clinical improvement in terms of more rapid beneficial resolution of the disease.

The applicant maintained that Plazomicin also represents a substantial clinical improvement in improved safety outcomes. Patients treated with Plazomicin had a lower incidence of renal events (10 percent versus 41.7 percent when compared to colistin), fewer Treatment Emergent Adverse Events (TEAEs), specifically blood creatinine increases and acute kidney injury, and approximately 30 percent fewer serious adverse events were in the Plazomicin group. According to the applicant, other substantial clinical improvements demonstrated by the CARE study for use of Plazomicin in patients who had been diagnosed with BSI included lower rate of superinfections or new infections, occurring in half as many patients treated with Plazomicin versus colistin (28.6 percent versus 66.7 percent).

According to the applicant, the CARE study demonstrates decreased all-cause mortality and significantly reduced disease complications at day 28 (EOS) and day 60 for patients who had been diagnosed with BSI, in addition to a superior safety profile to colistin. However, the applicant stated that, with the achieved enrollment, this study was not powered to support formal hypothesis testing and p-values and 90 percent confidence intervals are provided for descriptive purposes. The total number of patients who had been diagnosed with BSI was 29, with 14 receiving Plazomicin and 15 receiving colistin. While we understand the difficulty enrolling a large number of patients who have been diagnosed with BSI caused by CRE due to severity of the illness and the need for administering treatment promptly, we are concerned that results indicating reduced mortality and treatment advantages over existing standard of care for patients who have been diagnosed with BSI due to CRE are not statistically significant due to the small sample size. Therefore, we are concerned that the results from the CARE study cannot be used to support substantial clinical improvement.

The EPIC clinical trial was a randomized, multi-center, multi-national, double-blind study evaluating the efficacy and safety of Plazomicin compared with meropenem in the treatment of patients who have been diagnosed with cUTI based on composite cure endpoint (achieving both microbiological eradication and clinical cure) in the microbiological modified intent-to-treat (mMITT) population. Patients received between 4 to 7 days of IV therapy, followed by optional oral therapy like levofloxacin (or any other approved oral therapy) as step down therapy for a total of 7 to 10 days of therapy. Test-of-cure (TOC) was done 15 to 19 days and late follow-up (LFU) 24 to 32 days after the first dose of IV therapy. Six hundred nine patients fulfilled inclusion criteria, and were randomized to receive either Plazomicin or meropenem, with 306 patients receiving Plazomicin and 303 patients receiving meropenem. Safety analysis included 303 (99 percent) Plazomicin patients and 301 (99.3 percent) meropenem patients. mMITT analysis included 191 (62.4 percent) Plazomicin patients and 197 (65 percent) meropenem patients; exclusion from mMITT analysis was due to lack of study-qualifying uropathogen, which were pathogens susceptible to both Plazomicin and meropenem. In the mMITT population, both groups were comparable in terms of gender, age, percentage of patients who had been diagnosed with cUTI/acute pyelonephritis (AP)/urosepsis/bacteremia/moderate renal impairment at baseline.

According to the applicant, Plazomicin successfully achieved the primary efficacy endpoint of composite cure (combined microbiological eradication and clinical cure). At the TOC visit, 81.7 percent of Plazomicin patients versus 70.1 percent of meropenem patients achieved composite cure; this was statistically significant with a 95 percent confidence interval. Plazomicin also demonstrated higher eradication rates for key resistant pathogens than meropenem at both TOC (89.4 percent versus 75.5 percent) and LFU (77 percent versus 60.4 percent), suggesting that the Plazomicin treatment benefit observed at TOC was sustained. Specifically, Plazomicin demonstrated higher eradication rates, defined as baseline uropathogen reduced to less than 104, against the most common gram-negative uropathogens, including ESBL producing (82.4 percent Plazomicin versus 75.0 percent meropenem) and aminoglycoside resistant (78.8 percent Plazomicin versus 68.6 percent meropenem) pathogens. This was statistically significant, although of note, as total numbers of Enterobacteriaceae exceeded population of mMITT (191 Plazomicin, 197 meropenem) this presumably included patients who were otherwise excluded from the mMITT population.

According to the applicant, importantly, higher microbiological eradication rates at the TOC and LFU visits were associated with a lower rate of clinical relapse at LFU for Plazomicin treated patients (3 versus 14, or 1.8 percent Plazomicin versus 7.9 percent meropenem), with majority of the meropenem failures having had asymptomatic bacteriuria; that is, positive urine cultures without clinical symptoms, at TOC (21.1 percent), suggesting that the higher microbiological eradication rate at the TOC visit in Plazomicin-treated patients decreased the risk of subsequent clinical relapse. Plazomicin decreased recurrent infection by four-fold compared to meropenem, suggesting improved patient outcomes, such as reduced need for additional therapy and re-hospitalization for patients who have been diagnosed with cUTI. The safety profile of Plazomicin compared to meropenem was similar. The applicant noted that higher bacteria eradication results for Plazomicin were not due to meropenem resistance, as only patients with isolates susceptible to both drugs were included in the study. According to the applicant, the EPIC clinical trial results demonstrate clear differentiation of Plazomicin from meropenem, an agent considered by some as a gold-standard for treatment of patients who have been diagnosed with cUTI in cases due to resistant pathogens.

While the EPIC clinical trial was a non-inferiority study, the applicant contended that statistically significant improved outcomes and lower clinical relapse rates for patients treated with Plazomicin demonstrate that Plazomicin meets the substantial clinical

improvement criterion for the cUTI indication. Specifically, according to the applicant, the efficacy results for Plazomicin combined with a generally favorable safety profile provide a compelling benefit-risk profile for patients who have been diagnosed with cUTI, and particularly those with infections due to resistant pathogens. Most patients enrolled in the EPIC clinical trial were from Eastern Europe. It is unclear how generalizable these results would be to patients in the United States as the susceptibilities of bacteria vary greatly by location. The applicant maintains that this is consistent with prior studies and is unlikely to have affected the results of the study because the pharmacokinetics of Plazomicin and meropenem are not expected to be affected by race or ethnicity. However, bacterial resistance can vary regionally and we are interested in how this data can be extrapolated to a majority of the U.S. population. It is also unknown how quickly resistance to Plazomicin might develop. Additionally, the microbiological breakdown of the bacteria is unknown without the full published results, and patients outside of the mMITT population were included when the applicant reported the statistically superior microbiological eradication rates of Enterobacteriaceae at TOC. We are concerned whether there is still statistical superiority of Plazomicin in the intended bacterial targets in the mMITT. Finally, because both Plazomicin and meropenem were also utilized in conjunction with levofloxacin, it is unclear to us whether combined antibiotic therapy will continue to be required in clinical practice, and how levofloxacin activity or resistance might affect the clinical outcome in both patient groups.

We are inviting public comments on whether Plazomicin meets the substantial clinical improvement criterion for patients who have been diagnosed with BSI and cUTI, including with respect to whether Plazomicin constitutes a substantial clinical improvement for the treatment of patients who have been diagnosed with BSI who have limited or no alternative treatment options, and whether statistically better outcomes at test-of-cure visit, including higher eradication rates for ESBL-producing pathogens, and lower rate of subsequent clinical relapses constitute a substantial clinical improvement for patients who have been diagnosed with cUTI.

We did not receive any public comments in response to the published notice in the **Federal Register** regarding the substantial clinical improvement criterion for Plazomicin or at the New Technology Town Hall meeting.

h. GIAPREZA™

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.

The applicant stated that shock is a life-threatening critical condition characterized by the inability to maintain blood flow to vital tissues due to dangerously low blood pressure (hypotension). Shock can result in organ failure and imminent death, such that mortality is measured in hours and days rather than months or years. Standard therapy for shock currently uses fluid and vasopressors to raise the mean arterial pressure (MAP). The two classes of standard of care (SOC) vasopressors are catecholamines and vasopressins. Patients do not always respond to existing standard of care therapies. Therefore, a diagnosis of shock can be a difficult and costly condition to treat. According to the applicant, 35 percent of patients who are diagnosed with shock fail to respond to standard of care treatment options using catecholamines and go on to second-line treatment, which is typically vasopressin. Eighty percent of patients on vasopressin fail to respond and have no other alternative treatment options. The applicant estimated that CMS covered charges to treat patients who are diagnosed with vasodilatory shock who fail to respond to standard of care therapy are approximately 2 to 3 times greater than the costs of other conditions, such as acute myocardial infarction, heart failure, and pneumonia. According to the applicant, one-third of patients in the intensive care unit are affected by vasodilatory shock, with 745,000 patients who have been diagnosed with shock being treated annually, of whom approximately 80 percent are septic.

With respect to the newness criterion, according to the applicant, the expanded access program (EAP), or FDA authorization for the ''compassionate use'' of an investigational drug outside of a clinical trial, was initiated August 8, 2017. GIAPREZA™ was granted Priority Review status 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. We note that the applicant has submitted a request for approval for a unique ICD-10-PCS code for the administration of GIAPREZA™ beginning in FY 2019. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving GIAPREZA™.

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, according to the applicant, GIAPREZA™ is the first synthetic formulation of human angiotensin II, a naturally occurring peptide hormone in the human body. Angiotensin II is one of the major bioactive components of the renin-angiotensin-aldosterone system (RAAS), which serves as one of the body's central regulators of blood pressure. Angiotensin II increases blood pressure through vasoconstriction, increased aldosterone release, and renal control of fluid and electrolyte balance. Current therapies for the treatment of patients who have been diagnosed with shock do not leverage the RAAS. The applicant asserted that GIAPREZA™ is a novel treatment with a unique mechanism of action relative to SOC treatments for patients who have been diagnosed with shock, which is adequate fluid resuscitation and vasopressors. Specifically, the two classes of SOC vasopressors are catecholamines like Norepinephrine, epinephrine, dopamine, and phenylephrine IV solutions, and vasopressins like Vasostrict® and vasopressin-sodium chloride IV solutions. Catecholamines leverage the sympathetic nervous system and vasopressin leverages the arginine-vasopressin system to regulate blood pressure. However, the third system that works to regulate blood pressure, the RAAS, is not currently leveraged by any available therapies to raise mean arterial pressure in the treatment of patients who have been diagnosed with shock. The applicant maintained that GIAPREZA™ is the first synthetic human angiotensin II approved by the FDA and the only FDA-approved vasopressor that leverages the RAAS and, therefore, GIAPREZA™ utilizes a different mechanism of action than currently available treatment options.

The applicant explained that GIAPREZA™ leverages the RAAS, which is a body system not used by existing vasopressors to raise blood pressure through inducing

vasoconstriction. We are concerned that GIAPREZA™'s general mechanism of action, increasing blood pressure by inducing vasoconstriction through binding to certain G-protein receptors to stimulate smooth muscle contraction, may be similar to that of norepinephrine, albeit leveraging a different body system. We are inviting public comments on whether GIAPREZA™ uses a different mechanism of action to achieve a therapeutic outcome with respect to currently available treatment options, including comments or additional information regarding whether the mechanism of action used by GIAPREZA™ is different from that of other treatment methods of stimulating vasoconstriction.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we believe that potential cases representing patients who may be eligible for treatment involving GIAPREZA™ would be assigned to the same MS–DRGs as cases representing patients who receive SOC treatment for a diagnosis of shock. As explained below in the discussion of the cost criterion, the applicant believed that potential cases representing patients who may be eligible for treatment involving GIAPREZA™ would be assigned to MS–DRGs that contain cases representing patients who have failed to respond to administration of fluid and vasopressor therapies.

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, once patients have failed treatment using catecholamines, treatment options for patients who have been diagnosed with severe septic or other distributive shock are limited. Agents that were previously available are each associated with their own adverse events (AEs). The applicant noted that primary options that have been investigated include vasopressin, corticosteroids, methylene blue, and blood purification techniques. Of these options, the applicant stated that only vasopressin has a recommendation as add on vasopressor therapy in current treatment guidelines, but the recommendations are listed as weak with moderate quality of evidence. According to the applicant, there is uncertainty regarding vasopressin's effect on mortality due to mixed clinical trial results, and higher doses of vasopressin have been associated with cardiac, digital, and splanchnic ischemia. Therefore, the applicant asserted that there is a significant unmet medical need for treatments for patients who have been diagnosed with septic or distributive shock who remain hypotensive, despite adequate fluid and vasopressor therapy and for medications that can provide catecholamine-sparing effects.

The applicant also noted that there is currently no standard of care for addressing the clinical state of septic or other distributive shock experienced by patients who fail to respond to fluid and available vasopressor therapy. Additionally, no clinical evidence or consensus for treatments is available.

Based on the applicant's statements as summarized above, it appears that the applicant is asserting that GIAPREZA™ provides a new therapeutic treatment option for critically-ill patients who have been diagnosed with shock who have limited options and worsening prognosis. However, we are concerned that GIAPREZA™ may not offer a treatment option to a new patient population, specifically because the FDA approval for GIAPREZA™ does not reserve the use of GIAPREZA™ only as a last-line drug or adjunctive therapy for a subset of the patient population who have been diagnosed with shock who have failed to respond to standard of care treatment options. According to the FDA labeling, GIAPREZA™ is a vasoconstrictor to increase blood pressure in adult patients who have been diagnosed with septic or other distributive shock. Patients who have been diagnosed with septic or other distributive shock are not a new patient population. Therefore, it appears that GIAPREZA™ is used to treat the same or similar type of disease (a diagnosis of shock) and a similar patient population receiving SOC therapy for the treatment of shock. We are inviting public comments on whether GIAPREZA™ meets the substantial similarity criteria and the newness criterion.

With regard to the cost criterion, the applicant conducted an analysis for a narrower indication, patients who have been diagnosed with refractory shock who have failed to respond to standard of care vasopressors, and an analysis for a broader indication of all patients who have been diagnosed with septic or other distributive shock. We believe that only this broader analysis, which reflects the patient population for which the applicant's technology is approved by the FDA, is relevant to demonstrate that the technology meets the cost criterion and, therefore, we are only summarizing this broader analysis below. In order to identify the range of MS–DRGs that potential cases representing potential patients who may be eligible for treatment using GIAPREZA™ may map to, the applicant used two separate analyses to identify the MS–DRGs for patients who have been diagnosed with shock or related diagnoses. The applicant also performed three sensitivity analyses on the MS–DRGs for each of the two selections: 100 Percent of the MS–DRGs, 80 percent of the MS–DRGs, and 25 percent of the MS–DRGs. Therefore, a total of six scenarios were included in the cost analysis.

The first analysis (Scenario 1) selected the MS–DRGs most representative of the potential patient cases where treatment involving GIAPREZA™ would have the greatest clinical impact and outcomes of improvement over present treatment options. The applicant searched for 28 different ICD–9–CM codes under this scenario. The second analysis (Scenario 2) used the 80 most relevant ICD–9–CM diagnosis codes based on the inclusion criteria of the GIAPREZA™ Phase III clinical trial, ATHOS–3, and an additional 8 ICD–9–CM diagnosis codes for clinical presentation associated with vasodilatory or distributive shock patients failing fluid and standard of care therapy to capture any additional potential cases that may be applicable based on clinical presentations associated with this patient population.

Among only the top quartile of potential patient cases, the single MS–DRG representative of most potential patient cases was MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 Hours with MCC) for both ICD–9–CM diagnosis code selection scenarios, and in both selections, it accounted for a potential patient case percentage surpassing 25 percent. Because GIAPREZA™ is not reserved exclusively as a last-line drug based on the FDA indication, the applicant removed 50 percent of drug charges for prior technologies or other charges associated with prior technologies from the unstandardized charges before standardization in order to account for other drugs that may be replaced by the use of GIAPREZA™. The applicant has not yet supplied CMS with pricing for GIAPREZA™ and did not include charges for the new technology when conducting this analysis. For all analyses' scenarios, the applicant standardized charges using the FY 2015 impact file and then inflated the charges to FY 2019 using an inflation factor of 15.4181 percent (or 1.154181) by multiplying the inflation factor of 1.098446 in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57286) by the inflation factor of 1.05074 in the FY 2018 IPPS/LTCH PPS final rule (82 FR

38524). The final inflated average case-weighted standardized charge per case was calculated for each scenario and compared with the average case-weighted threshold amount for each group of MS–DRGs based on the thresholds in Table 10.

Results of the analyses for each of the two code selection scenarios, each with three sensitivity analyses for a total of six analyses, are summarized in the tables below:

	Number of MS–DRGs assessed	Number of Medicare cases	Case-weighted new technology add-on payment threshold	Final average inflated standardized charge per case	Amount exceeded threshold
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 1					
ICD–9–CM Diagnosis Code Selection (28 Codes):					
100 Percent	439	120,966	$77,427	$77,427	$34,095
80 Percent	10	96,102	77,641	100,167	22,526
25 Percent	1	66,980	53,499	71,951	18,452
Cost Analysis Based on ICD–9–CM Diagnosis Code Scenario 2					
ICD–9–CM Diagnosis Code Selection (88 Codes):					
100 Percent	466	164,892	78,675	112,174	33,499
80 Percent	52	131,690	79,732	108,396	28,664
25 Percent	1	67,016	53,499	71,688	18,189

The applicant maintained that, based on the Table 10 thresholds, the inflated average case-weighted standardized charge per case in the analyses exceeded the average case-weighted threshold amount. The applicant noted that the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount by at least $18,189, without the average per patient cost of the technology. As such, the applicant anticipated that the inclusion of the cost of GIAPREZA™, at any price point, would further increase charges above the average case-weighted threshold amount. Therefore, the applicant stated that the technology meets the cost criterion. We note that we are unsure whether the selection in both scenarios fully captures the broader indication for which the FDA approved the use of GIAPREZA™. We are inviting public comments on whether GIAPREZA™ meets the cost criterion, including with respect to the concern we have raised.

With respect to the substantial clinical improvement criterion, the applicant summarized that it believes that GIAPREZA™ represents a substantial clinical improvement because it: (1) Addresses an unmet medical need for patients who have been diagnosed with septic or distributive shock that, despite standard of care vasopressors, are unable to maintain adequate mean arterial pressure; (2) is the only agent shown in randomized clinical trial to rapidly and sustainably achieve or maintain target blood pressure in patients who do not respond adequately to fluid and vasopressor therapy; (3) although not powered for mortality, the ATHOS–3 trial demonstrated a strong trend to reduce the risk of death in adults from septic or distributive shock who remain hypotensive despite fluid therapy and vasopressor therapy, a severe, life-threatening condition, for which there are no other therapies; (4) provides a catecholamine-sparing effect; and (5) is generally safe and well-tolerated, with no significant differences in the percentages of patients with any grade adverse events or serious adverse events when compared to placebo.

With regard to expanding on the statements above, the applicant believes that the use of GIAPREZA™ offers clinicians a significant new tool to manage and treat severe hypotension in all adult patients who have been diagnosed with septic or other distributive shock who are unresponsive to existing vasopressor therapies. The applicant also stated that the use of GIAPREZA™ provides a new therapeutic option for critically-ill adult patients who have been diagnosed with septic or other distributive shock who have limited options and worsening prognoses.

The applicant maintained that GIAPREZA™ was shown to be an effective treatment option for critically-ill patients who have been diagnosed with refractory shock. The applicant reported that a randomized, double-blind placebo controlled trial called ATHOS–3 [154] examined the ability of GIAPREZA™ to increase mean arterial pressure (MAP), with the primary endpoint being achievement of a MAP of greater than or equal to 75 mmHg (the research-backed guideline set by the Surviving Sepsis Campaign) or a 10 mmHg increase in baseline MAP. Significantly more patients in the treatment arm met the primary endpoint (69.9 percent versus 23.4 percent, $P<0.001$). The applicant asserted that this MAP improvement constitutes a significant substantial clinical improvement because patients treated with GIAPREZA™ were three times more likely to achieve acceptable blood pressure than patients receiving the placebo. The MAP significantly and rapidly increased in patients treated with GIAPREZA™ and was sustained over 48 hours consistent across subgroups and the treatment effect of GIAPREZA™ was confirmed using multivariate analysis. The group treated with GIAPREZA™ also experienced a greater mean increase in MAP; the MAP increased by a mean of 12.5 mmHg for the GIAPREZA™ group compared to a mean of 2.9 mmHg for the placebo group.

Second, the applicant maintained that GIAPREZA™ demonstrated potential improvement in organ function by lowering the cardiovascular sequential organ failure assessment (SOFA) scores of patients at 48 hours (-1.75 GIAPREZA™ group versus -1.28 placebo group). However, we are concerned that lower cardiovascular SOFA scores may not demonstrate substantial clinical improvement because there was no difference in the improvement of other components of

[154] Khanna, A., English, S.W., Wang, X.S., et al., ''Angiotensin II for the treatment of vasodilatory shock,'' [supplementary appendix] [published online ahead of print May 21, 2017], *N Engl J Med.,* 2017, doi: 10.1056/NEJMoa1704154.

the SOFA score or the overall SOFA score.

Third, the applicant asserted that GIAPREZA™ represents a substantial clinical improvement because the use of GIAPREZA™ reduced the need to increase overall doses of catecholamine vasopressors. The applicant stated that patients receiving higher doses of catecholamine vasopressors suffer from cardiac toxicity, organ dysfunction, and other metabolic complications that are associated with higher mortality. By decreasing the overall dosage of catecholamine vasopressors, GIAPREZA™ potentially reduces the adverse effects of vasopressors. The mean change in catecholamine vasopressors in patients receiving GIAPREZA™ versus patients receiving the placebo at 3 hours was −0.03 versus 0.03 (P<0.001), showing that GIAPREZA™ allowed for catecholamines to be titrated down, while patients not receiving GIAPREZA™ required additional catecholamine doses. The vasopressor mean doses were consistently lower in the GIAPREZA™ group, and at 48 hours, vasopressors had been discontinued in 28.5 percent of patients in the placebo group versus 40.5 percent of the GIAPREZA™ group. We note that, while GIAPREZA™ may potentially reduce certain adverse effects associated with SOC treatments, the FDA labeling cautions that the use of GIAPREZA™ can cause dangerous blood clots with serious consequences (clots in arteries and veins, including deep venous thrombosis); according to the FDA label, prophylactic treatment for blood clots should be used.

The applicant stated that while the study was not powered to detect mortality effects, there was a nonsignificant trend toward longer survival in the GIAPREZA™ group. Overall mortality rates at 7 days and 8 days in the modified intent to treat (MITT) population were 22 percent less in the GIAPREZA™ group than in the placebo group. At 28 days, the mortality rate in the placebo group was 54 percent versus 46 percent in the GIAPREZA™ group. However, the p-values for the decrease in mortality with GIAPREZA™ at 7 days, 8 days, and 28 days did not demonstrate statistical significance.

The applicant concluded that GIAPREZA™ is the first commercial product to increase blood pressure in adults who have been diagnosed with septic or other distributive shock that leverages the renin-angiotensin-aldosterone system. The applicant stated that the results of the ATHOS–3 study provide support for a well-tolerated new therapeutic agent that demonstrates significant improvements in mean arterial pressure. Additionally, the applicant noted that hypotension in adults who have been diagnosed with septic or other distributive shock is a prevalent life-threatening condition where therapeutic options are limited and a high unmet medical need exists. The applicant stated that the use of GIAPREZA™ will represent a safe and effective new therapy that not only leverages a system that current therapies are not utilizing, but also offers a viable alternative where one does not exist.

We understand that, in this heterogeneous and difficult to treat patient population, studies assessing mortality as a primary endpoint are difficult, and as such, surrogate endpoints (that is, achieving baseline MAP) have been explored to assess the efficacy of treatments. While the outcomes presented by the applicant, such as achieving target MAP, lower SOFA scores, and reduced catecholamine usage, could be surrogates for clinical outcomes in these patients, there is not a strong pool of evidence connecting these single data points directly with morbidity and mortality. Therefore, we are unsure whether achieving target MAP, lower SOFA scores, and reduced catecholamine usage represents a substantial clinical improvement or instead short-term, temporary improvements without a change in overall patient prognosis.

In response to this concern about MAP constituting a meaningful measure for substantial clinical improvement, the applicant supplied additional information from the current Surviving Sepsis guidelines, which recommend an initial target MAP of 65 mmHg. The applicant explained that as MAP falls below a critical threshold, inadequate tissue perfusion occurs, potentially resulting in multiple organ dysfunction and death. Therefore, early and adequate hemodynamic support and treatment of hypotension is critical to restore adequate organ perfusion and prevent worsening organ dysfunction and failure. In diagnoses of septic or distributive shock, the goal of treatment is to increase and maintain a threshold MAP in order to improve tissue perfusion. According to the applicant, tissue perfusion becomes linearly dependent on arterial pressure below a threshold MAP. In patients who have been diagnosed with septic shock requiring vasopressors, the current Surviving Sepsis guidelines are based on available evidence that demonstrates that adequate MAP is important to clinical outcomes and that prolonged decreases in MAP below 65 mmHg is associated with poor outcome. According to information supplied by the applicant, even short durations like less than 5 minutes of low MAP have been associated with severe outcomes, such as myocardial infarction, stroke, and acute kidney injury. The applicant stated that a retrospective study [155] found that MAP was independently related to ICU and hospital mortality in patients with severe sepsis or septic shock.

Finally, we are concerned that the study results may demonstrate substantial clinical improvement only for patients who are unresponsive to the administration of fluids and vasopressors because patients were only included in the ATHOS–3 study if they failed fluids and vasopressors, rather than for the broader patient population of adult patients who have been diagnosed with septic or other distributive shock for which GIAPREZA™ was approved by the FDA for use as an available treatment option. The applicant continues to maintain that the use of GIAPREZA™ has significant efficacy in improving blood pressure for patients who have been diagnosed with distributive shock, while decreasing adrenergic vasopressor usage, thereby, providing another avenue for therapy in this difficult to treat patient population. However, we are still concerned that the results from the clinical trial may be too narrow to accurately represent the entire patient population that has been diagnosed with septic or other distributive shock and, therefore, we are concerned that the clinical trial's results may not adequately demonstrate that GIAPREZA™ is a substantial clinical improvement over existing therapies for all the patients for whom the treatment option is indicated. We are inviting public comments on whether GIAPREZA™ meets the substantial clinical improvement criterion.

We did not receive any public comments in response to the published notice in the **Federal Register** regarding the substantial clinical improvement criterion for GIAPREZA™ or at the New Technology Town Hall meeting.

i. GammaTile™

Isoray Medical, Inc. and GT Medical Technologies, Inc. submitted an application for new technology add-on payments for FY 2019 for the GammaTile™. (We note that Isoray

[155] Walsh, M., Devereaux, P.J., Garg, A.X., et al., ''Relationship between Intraoperative Mean Arterial Pressure and Clinical Outcomes after Noncardiac Surgery Toward an Empirical Definition of Hypotension,'' *Anesthesiology,* 2013, vol. 119(3), pp. 507–515.

Medical, Inc. and GammaTile, LLC previously submitted an application for new technology add-on payments for GammaTile™ for FY 2018, which was withdrawn prior to the issuance of the FY 2018 IPPS/LTCH PPS final rule.) The GammaTile™ is a brachytherapy technology for use in the treatment of patients who have been diagnosed with brain tumors, 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 brain tumors. According to the applicant, the GammaTile™ technology is a new vehicle of delivery for and inclusive 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 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 applicant for the GammaTile™ technology anticipates FDA clearance by the spring of 2018. In its application, the applicant indicated that it anticipated that the product would be cleared by the FDA for use in both the primary and salvage treatment of radiosensitive malignances of the brain. However, in discussions with the applicant, the applicant indicated that it is only anticipating FDA clearance for use in the salvage treatment of recurrent radiosensitive malignances of the brain. 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 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 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 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 stated that when compared to treatment using external beam radiation therapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. The applicant explained that the GammaTile™ technology is fundamentally different in structure, function, and safety from all external beam radiation therapies, and delivers treatment through a different mechanism of action. In contrast to external beam radiation modalities, the applicant further explained that the GammaTile™ is a form of internal radiation termed brachytherapy. Brachytherapy treatments are performed using radiation sources positioned very close to the area requiring radiation treatment and only deliver radiation to the tissues that are immediately adjacent to the margin of the surgical resection. For this reason, brachytherapy is a current standard of care treatment for many non-central nervous system tumors, including breast, cervical, and prostate cancers.

Due to the custom positioning of the radiological sources and the use of the cesium-131 isotope, the applicant noted that the GammaTile™ technology focuses therapeutic levels of radiation on an extremely small area of the brain. Unlike all external beam techniques, the applicant stated that this radiation does not pass externally inward through the skull and healthy areas of the brain to reach the targeted tissue and, therefore, may limit neurocognitive deficits seen with the use of external beam techniques. Because of the rapid reduction in radiation intensity that is characteristic of cesium-131, the applicant asserted that the GammaTile™ technology can target the margin of the excision with greater precision than any alternative treatment option, while sparing healthy brain tissue from unnecessary and potentially damaging radiation exposure.

The applicant also stated that, when compared to other types of brain brachytherapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. The applicant explained that cancerous cells at the margins of a tumor resection cavity can also be irradiated with the placement of brachytherapy sources in the tumor cavity. However, the applicant asserted that the GammaTile™ technology is a pioneering form of brachytherapy for the treatment of brain tumors that uses the isotope cesium-131 embedded in a collagen implant that is customized to the geometry of the brain cavity. According to the applicant, use of cesium-131 and the custom distribution of seeds in a three-dimensional collagen device result in a unique and highly effective delivery of radiation therapy to brain tissue.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the GammaTile™ technology is a treatment option for patients who have been diagnosed with brain tumors that progress locally after initial treatment with external beam radiation therapy, and potential cases representing patients that may be eligible for treatment involving this technology are assigned to the same MS–DRG (MS–DRG 23 (Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemotherapy Implant)) as other current treatment forms of brachytherapy and external beam radiation therapy.

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 stated that the GammaTile™ technology offers a treatment option for a patient population with limited, or no other, available treatment options. The applicant explained that treatment options for patients who have been diagnosed with brain tumors that progress locally after initial treatment with external beam radiation therapy are limited, and there is no current standard of care in this setting. According to the applicant, surgery alone for recurrent tumors may provide symptom relief, but does not remove all of the cancer cells. The applicant further stated that repeating external beam radiation therapy for adjuvant treatment is hampered by an increasing risk of brain injury because additional external beam radiation therapy will increase the

total dose of radiation to brain tissue, as well as increase the total volume of irradiated brain tissue. Secondary treatment with external beam radiation therapy is often performed with a reduced and, therefore, less effective dose. The applicant stated that the technique of implanting cesium-131 seeds in a collagen matrix is currently only available to patients in one location, and requires a high degree of expertise to implant. The manufacturing process of the GammaTile™ will greatly expand the availability of treatment beyond research programs at highly specialized cancer treatment centers.

Based on the above, the applicant concluded that the GammaTile™ technology is not substantially similar to other existing technologies and meets the newness criterion.

However, we are concerned that the mechanism of action of the GammaTile™ may be the same or similar to current forms or radiation or brachytherapy. Specifically, while the placement of the cesium-131 source (or any radioactive source) in a collagen matrix offset may constitute a new delivery vehicle, we are concerned that this sort of improvement in brachytherapy for the use in the salvage treatment of radiosensitive malignancies of the brain may not represent a new mechanism of action.

We are inviting public comments on whether GammaTile™ meets the substantial similarity criteria and the newness criterion.

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 25 through 27 (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 FY 2017 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.05074 by the age of each case (that is, the factor was applied to 2015 claims 3 times and 2016 claims 2 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 $246,310 exceeds the average case-weighted threshold amount of $141,249 for MS–DRG 23, the MS–DRG that would be assigned for cases involving placement of the GammaTile™ device.

The applicant also noted that its analysis does not include a reduction in costs due to reduced operating room times. The applicant stated that there is significant time and workload associated with assembling the device, and codes billed for this work are paid at a flat rate. We are inviting public comments on 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. 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 option. 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. 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 described how the GammaTile™ technology improves clinical outcomes compared to existing treatment options, including external beam radiation therapy and other forms of brain brachytherapy. To demonstrate that the GammaTile™ technology represents a substantial clinical improvement over existing technologies, the applicant submitted data from three abstracts (described below), with one associated paper demonstrating feasibility or superior progression-free survival compared to the patient's own historical control rate.

In a presentation at the Society for Neuro-Oncology in November 2014 (Dardis, Christopher; Surgery and permanent intraoperative brachytherapy improves time to progression of recurrent intracranial neoplasms), 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 all patients had previously experienced re-growth 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, has not been reached (as this value can only be calculated when more than 50 percent of treated patients have failed the prescribed treatment).

A second set of outcomes on the prototype GammaTile™ was presented at the Society for Neuro-Oncology Conference on Meningioma in June 2016 (Brachman, David; Surgery and

permanent intraoperative brachytherapy improves time to progress of recurrent intracranial neoplasms). This study enrolled 16 patients with 20 recurrent grade 2 or 3 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, the median treatment site progression-free survival time after the prototype GammaTile™ treatment has 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 (Youssef, Emad; Cs131 implants for salvage therapy of recurrent high grade gliomas). In this study, 13 patients who were diagnosed with recurrent high-grade gliomas (9 with glioblastoma and 4 with grade 3 astrocytoma) were treated in an identical manner to the cases described above. 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 has 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.

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 asserted that, when considered in total, the data reported in these three studies 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.

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 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 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 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.

The applicant further summarized how the GammaTile™ technology is a substantial clinical improvement over existing treatment options as: (1) Providing a treatment option for patients with no other available treatment options; (2) reducing rate of mortality compared to alternative treatment options; (3) reducing 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.

Based on consideration of all of the data presented above, the applicant believed that the use of the GammaTile™ technology represents a substantial clinical improvement over existing technologies. The studies were limited to patients who have been diagnosed with recurrent tumors after previous surgical resection. As previously discussed, the applicant explained that it is anticipating FDA clearance for the use of the GammaTile™ only in the treatment of recurrent malignancies.

We are concerned with the limited nature of the clinical efficacy and safety data provided by the applicant. The findings presented appear to be derived from relatively small case-studies. While the applicant described increases in median time to disease recurrence in support of improvement, we are concerned with regard to the lack of analysis, meta-analysis, or statistical tests that indicated that seeded brachytherapy procedures represented a statistically significant improvement over alternative treatments, as limited as they may be. We also are concerned with the lack of studies involving the actual manufactured device. In addition, we are concerned that the applicant referenced various findings in its application, but did not include relevant reference materials to substantiate those findings. For instance, the applicant made statements regarding the low complication rates with the use of GammaTile™ prototypes, without any discussion of average rates with comparison to other alternative treatments.

We are inviting public comments on whether GammaTile™ meets the substantial clinical improvement criterion.

We did not receive any public comments on the GammaTile™ technology in response to the published notice in the **Federal Register** or at the New Technology Town Hall Meeting.

j. Supersaturated Oxygen (SSO_2) Therapy (DownStream® System)

TherOx, Inc. submitted an application for new technology add-on payments for the Supersaturated Oxygen (SSO_2) Therapy (the DownStream® System) for FY 2019. The DownStream® System is an adjunctive therapy designed to ameliorate progressive myocardial necrosis by minimizing microvascular damage in patients who have received treatment for a diagnosis of acute myocardial infarction (AMI) following percutaneous intervention (PCI) with coronary artery stent placement. The applicant stated that, while contemporary therapies for patients who have received treatment for a diagnosis of AMI have focused on relieving blockages and improving blood flow to the diseased myocardium, little has been done to provide localized hyperbaric oxygen to ischemic tissue. According to the applicant, patients who have received treatment for a diagnosis of AMI are at high risk for reduced quality of life, heart failure, and higher mortality as a result of the extent of necrosis or infarct size experienced in the myocardium during the infarction. The applicant asserted that the net effect of the SSO_2 Therapy is to reduce the infarct size and, therefore, preserve heart muscle.

The 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 then 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 (pO2) 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).

According to the applicant, the SSO_2 Therapy has been designated as a Class III medical device (high risk) by the FDA. The applicant indicated that it expects to receive pre-market approval from the FDA in the first quarter of 2018. The applicant asserted 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 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 purposes of new technology add-on payments. According to the applicant, the SSO_2 Therapy is administered adjunctively immediately following completion of successful PCI. The applicant maintained that currently available treatment options for patients who have been diagnosed and begun initial treatment for AMI involve the revascularization of the blocked coronary artery by means of either thrombolytic therapy or PCI with stent placement accompanied by the administration of adjunctive pharmacologic agents such as glycoprotein IIb/IIIa inhibitors, or via coronary artery bypass graft (CABG) surgery. The applicant asserted that because there are no other approved therapies for patients who have been diagnosed with AMI *post*-PCI, the SSO_2 Therapy meets the newness criterion. Below we evaluate the applicant's assertions with respect to whether the SSO_2 Therapy meets each of the three substantial similarity criteria.

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, the SSO_2 Therapy employs two mechanisms of action: (1) First, the increased oxygen levels re-open the microcirculatory system within the infarct zone, which has experienced ischemia during the occlusion period; and (2) second, once reopened, the blood flow contains additional oxygen to restart the metabolic processes within the stunned myocardium. The applicant asserted that these mechanisms have been studied in preclinical investigations sponsored by the applicant, where controlled studies were performed in both porcine and canine AMI models to determine the safety, effectiveness, and mechanism of action of the SSO_2 Therapy. According to the applicant, the findings of these studies demonstrated improved left ventricular function, infarct size reduction, a microvascular mechanism of action, and that the SSO_2 Therapy is nontoxic. Based on the information provided by the applicant, current

treatment options for patients who have been diagnosed and receive treatment for AMI function to restore coronary artery blood flow, which addresses macrovascular disease but not the underlying cellular changes resulting from hypoxia. The applicant maintains that currently available treatment options for patients who have been diagnosed and receive treatment for AMI do not treat hypoxemic damage at the microvascular or microcirculatory level, and that SSO_2 Therapy does not use the same or a similar mechanism of action as any existing treatment available for patients who have been diagnosed and receive treatment for a diagnosis of AMI.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, we believe that potential cases involving the SSO_2 Therapy may be assigned to the same MS–DRG(s) as other cases involving PCI with stent placement also used to treat patients who have been diagnosed with AMI.

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 asserted that, in spite of many advances and refinements in PCI for reopening the blocked coronary artery, patients who have been diagnosed and receiving treatment for AMI are at high risk for reduced quality of life, heart failure, and higher mortality, as a result of the extent of necrosis experienced in the myocardium during the infarction. According to the applicant, patients who have been diagnosed with and receiving treatment for AMI continue to experience elevated early and late Major Adverse Cardiac Events (MACE), as well as a higher risk for congestive heart failure (CHF) development. The applicant made the following assertions: The net effect of the SSO_2 Therapy is to reduce the infarct size, or extent of necrosis, in the myocardium *post*-AMI and, therefore, improve left ventricular function, leading to improved patient outcomes; there are no other approved therapies for patients who have been diagnosed with and receive treatment for AMI *post*-PCI and submitted data evaluating the SSO_2 Therapy directly as compared to the currently available standard of care, PCI with stenting alone; and SSO_2 Therapy's emphasis is on treating patients who have been diagnosed with AMI at the microvascular level instead of reopening the blocked coronary artery at the macrovascular level as with other treatments and that it, therefore, treats a different type of disease than currently available treatment options for patients who have been diagnosed with and receive treatment for AMI.

We are inviting public comments on whether the SSO_2 Therapy 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. In order to identify the range of MS–DRGs to which potential cases representing potential patients who may be eligible for treatment involving the SSO_2 Therapy may map, the applicant identified all MS–DRGs for cases of patients who have been diagnosed with anterior STEMI as a principal diagnosis. Specifically, the applicant searched the FY 2016 MedPAR file for claims reporting diagnoses of anterior STEMI by ICD–10–CM diagnosis codes I21.0 (ST elevation myocardial infarction of anterior wall), 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 primary diagnosis. The applicant identified 11,030 potential cases across 4 MS–DRGs, with approximately 86 percent of all potential cases mapping to the following 2 MS–DRGs: MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Vessels/Stents) and MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC). The remaining 14 percent of potential cases mapped to MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent with MCC or 4+ Vessels/Stents) and MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC).

Using the 11,030 identified cases, the applicant determined that the average unstandardized case-weighted charge per case was $94,290. The applicant then standardized the charges. The applicant did not remove charges for the current treatment because, as discussed above, the SSO_2 Therapy will be used as an adjunctive treatment option following successful PCI with stent placement. The applicant then applied the inflation factor of 1.05074 from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524) 3 times to inflate the charges from FY 2016 to FY 2019. The applicant added charges related to the new technology, which accounts for the use of 1 cartridge per patient, as well as the 60 minutes of procedure time, to the average charges per case. Based on the FY 2018 IPPS/LTCH PPS final rule Table 10 threshold amounts, the average case-weighted threshold amount was $91,064. The inflated average case-weighted standardized charge per case was $146,974. 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 are inviting comments on whether or not the SSO_2 Therapy meets the cost criterion.

With regard to the substantial clinical improvement criterion, according to the applicant, the preferred standard of care for the treatment of patients who have been diagnosed with AMI involves the revascularization of the blocked coronary artery by means of PCI with stent placement, accompanied by the administration of adjunctive pharmacologic agents such as antiplatelet drugs, including glycoprotein IIb/IIIa inhibitors. The applicant stated that the clinical unmet need for these patients, particularly patients who have been diagnosed with anterior wall STEMI with the greatest potential impact to their ventricle, is to provide incremental therapeutic benefit beyond PCI with stenting to reduce the damage to their myocardium. The applicant believed that SSO_2 Therapy fulfills this unmet clinical need in the treatment of patients who have been diagnosed with ST-elevation AMI by reducing infarct size as compared to the standard of care, PCI with stenting alone.

The applicant asserted that, as an adjunctive treatment, the SSO_2 Therapy has demonstrated superiority over PCI with stenting alone in reducing the infarct size for high-risk patients diagnosed with anterior AMI treated within 6 hours of symptom onset. The applicant also noted that the SSO_2 Therapy has been shown to preserve left ventricular integrity as compared to patients who receive treatment involving PCI with stenting alone, utilizing direct measurements of left ventricular volume over the 30-day post-procedure period. The applicant noted that the quantification of the extent of necrosis or infarction in the muscle is the best physical measure of the consequences of AMI for patients in post-intervention, as the infarct size is the quantification of the extent of scarring of the left ventricle *post*-AMI and, therefore, provides a direct measure of the health of the

myocardium and indirectly on 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. The applicant highlighted the importance of the SSO_2 Therapy's mechanism of action, which treats hypoxemic damage at the microvascular or microcirculatory level, by noting that the degree to which microvascular impairment in the myocardium is irreversible and unaffected by therapeutic intervention leads to a greater extent of infarction. Furthermore, the applicant noted that compromised microvascular flow remains a serious problem in STEMI care and leads to microvascular obstruction (MVO), which a recent study has shown to be an important independent predictor of mortality and heart failure (HF) hospitalization at 1 year. The applicant asserted that MVO is closely tied to the resultant damage or infarct size in patients diagnosed with acute STEMI and is of critical importance to address mechanistically in any treatment administered in conjunction to PCI, to effect an improved outcome in primary care.

The applicant performed controlled studies in both porcine and canine AMI models to determine the safety, effectiveness, and mechanism of action of the SSO_2 Therapy. The key summary points from these animal studies are:

- The 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.
- The 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.
- The 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.
- The 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 was observed in the SSO_2-treated animals versus controls, which indicate improvement in underlying myocardial hypoxia.
- Transmission electron microscopy (TEM) photographs have shown amelioration of endothelial cell edema and restoration of capillary patency in ischemic zone cross-sectional histological examination of the SSO_2-treated animals, while nontreated controls exhibit significant edema and vessel constriction at the microvascular level.

The applicant also submitted results from five clinical studies that it asserted demonstrate the substantial clinical benefit associated with the SSO_2 Therapy. These studies include the Phase I/IA feasibility trial, the European OYSTER–AMI study, the AMIHOT I and AMIHOT II randomized trials, and the IC–HOT clinical study.

The Phase I/IA and OYSTER–AMI studies demonstrated that the SSO_2 Therapy held promise in improving left ventricular function, especially in the infarct zone, for patients who have been diagnosed with and receiving treatment for AMI. Specifically, an IDE-sanctioned Phase I pilot study was conducted in the United States and Italy involving 29 patients who had been diagnosed with and receiving treatment involving the SSO_2 Therapy for anterior AMI and found significant LV functional improvement over time as noted in the 2–D echocardiography analysis of the combined Phase I/IA data. Baseline measurements of ejection fraction (EF) and wall motion score index (WMSI) were taken immediately *post*-PCI prior to SSO_2 Therapy administration. An improving trend in EF and significant improvement in WMSI were observed at 24-hours after SSO_2 Therapy administration, and further improvement in ventricular function was demonstrated at 1 and 3 months compared to baseline. The analysis demonstrated that these improvements in global LV functional measures were due to recovery of ventricular function in the infarct zone; regional WMSI assessments showed no change in the noninfarct zone. Similar results were found in the European OYSTER–AMI trial, which assessed supersaturated oxygen in reperfused ST-elevation AMI, directing attention to 41 patients receiving treatment involving the SSO_2 Therapy versus untreated controls. The study showed that the supersaturated oxygen treatment group had a significantly faster cardiac enzyme and ST segment elevation reduction, therefore suggesting an improvement in microvascular reperfusion. The SSO_2 Therapy treatment group also showed a significantly better improvement in left ventricular wall motion and ejection fraction,[156] which a number of studies have shown to be directly related to mortality.[157] The OYSTER–AMI study further suggested that the SSO_2 Therapy reduces the infarct size, as demonstrated in reduced cardiac enzyme CK and CK–MB release.

The AMIHOT I clinical trial was designed as a prospective, randomized evaluation of patients who had been diagnosed with and receiving treatment for AMI presenting within 24 hours of symptom onset, including both anterior and inferior patients diagnosed with AMI. The AMIHOT I trial was conducted with IDE approval from FDA. The study included 269 randomized patients, with 3 independent biomarkers (infarction size reduction, regional wall motion score improvement at 3 months, and reduction in ST segment elevation) designated as co-primary endpoints to evaluate the effectiveness of the SSO_2 Therapy. The study was designed to demonstrate superiority of the SSO_2 Therapy group as compared to controls for each of these endpoints, and to demonstrate non-inferiority of the SSO_2 Therapy group as compared to control with respect to 30-day MACE. The study population was comprised of qualifying patients who had been diagnosed with AMI and receiving treatment with either PCI alone or with the SSO_2 Therapy as an adjunct to successful PCI within 24 hours of symptom onset. According to the applicant, results for the control/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. 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 three co-primary endpoints as compared to the control group. Key safety data revealed no statistically significant differences in the composite primary endpoint of 1-month (30 days) Major Adverse Cardiac Event (MACE) rates between the SSO_2 Therapy and control groups. MACE includes the combined incidence of death, reinfarction, target vessel revascularization, and stroke. In total, 9/134 (6.7 percent) patients in the SSO_2 Therapy group and 7/135 (5.2 percent) patients in the control group experienced 30-day MACE (p=0.62).

[156] Bartorelli, A.L., ''Hyperoxemic Perfusion for Treatment of Reperfusion Microvascular Ischemia in Patients with Myocardial Infarction,'' *Am J Cardivasc Drugs,* 2003, vol. 3(4), pp. 253–6.

[157] Stone, G.W., et al., ''Relationship between infarct size and outcomes following primary PCI: Patient-level analysis from 10 randomized trials,'' *J Am Coll Cardio,* vol. 67.14, 2016, pp. 1674–1683.

Another pivotal trial in the evaluation of the SSO_2 Therapy, 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. 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 with the 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 noninferiority in the 30-day MACE rate, comparing the SSO_2 Therapy group with the control group, within a safety delta of 6.0 percent. 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 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. We are interested in information regarding at what timeframe in the study was the reduction of infarct size measured. In addition, the applicant stated that the finding of device effectiveness was supported by additional analyses that showed a 53 percent increased likelihood of having a small infarct among the SSO_2 therapy patients.[158] In assessing 30-day Major Adverse Cardiac Events (MACE), while higher in the SSO_2 Therapy group, the rates were statistically noninferior (5.4 percent versus 3.8 percent). However, given the higher 30-day MACE outcome among the SSO_2 Therapy patients in both the AMIHOT I and AMIHOT II trials, we are concerned about the lack of long-term data on improvement in patient clinical outcomes, despite the lack of statistical significance.

The applicant also submitted 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 was 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 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. Furthermore, according to the applicant, 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). 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. 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. The applicant asserted that the IC–HOT clinical trial data continue to demonstrate substantial clinical benefit of the SSO_2 Therapy as compared to the standard of care, PCI with stenting alone.

We are inviting public comments on whether the SSO_2 Therapy meets the substantial clinical improvement criterion.

Below we summarize and respond to written public comments we received regarding the DownStream® System during the open comment period in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: A number of commenters supported the approval of new technology add-on payments for the DownStream® System (SSO_2 Therapy) for the treatment of patients diagnosed with AMI. The commenters asserted that SSO_2 Therapy is effective at significantly reducing infarct size in patients diagnosed with anterior wall myocardial infarction who have been treated with primary percutaneous intervention. The commenters reiterated the results of the AMIHOT II randomized trial which demonstrated that treatment with SSO_2 Therapy following successful PCI in patients diagnosed with an anterior wall myocardial infarction resulted in a 6.5 percent absolute reduction and a 26 percent relative reduction in infarct size, compared to treatment with PCI alone (the percentages above are based on a 26.5 percent median infarct size in the control PCI group versus 20 percent infarct size in the SSO_2 Therapy group). One commenter stated that the infarct size reduction of 6.5 percent documented in the AMIHOT II trial results is substantial when it comes to patient care. In addition, other commenters believed that SSO_2 Therapy is a safe treatment option because there was no significant difference in Major Adverse Cardiac Events (MACE) between the treatment and control groups.

The commenters also referenced the results from the IC–HOT confirmatory study. The commenters believed that the results of this study demonstrated stabilization of the left ventricular size with no dilatation at 30 days, which confirmed the efficacy and safety of SSO_2 Therapy. The commenters stated that, in a sample patient population of 98 patients diagnosed with anterior wall myocardial infarction, to achieve a result in infarct size of 19.4 percent of the left ventricular following use of SSO_2 Therapy is similar to the results achieved in the patients enrolled in the treatment group of the AMIHOT II trial and is also substantial to patient care. The commenters emphasized that patients diagnosed with anterior wall myocardial infarction are high-risk patients with a high mortality rate, and patients who survive experiences with large infarct size and left ventricular dysfunction eventually suffer congestive heart failure, ultimately requiring a defibrillator and have poor quality of life. The commenters also noted that the MRI results documented from the IC–HOT trial have shown a reduction in left ventricular volumes, suggesting the left ventricular cavity did not dilate and the ventricle remained stable, which is consistent with the experience of many of the commenters that treated patients using SSO_2 Therapy as part of the trial. Another commenter noted that 25 percent of the patients in the IC-HOT trial had a normal ejection fraction at follow-up MRI scan. The commenters believed that SSO_2 Therapy should be a standard-of-care, given the low number of adverse events and the low instances of new heart failure admissions in their

[158] Stone, G.W., Martin, J.L., Boer, M.J., et al., ''Effect of Supersaturated Oxygen Deliver on Infarct Size After Percutaneous Coromary Intervention in Acute Myocardial Infarction,'' *Cir Cardiovasc Interv,* 2009, vol. 2, pp. 366–75.

experience with the use of SSO_2 Therapy.

Another commenter provided additional clinical studies in response to a question presented at the New Technology Town Hall meeting regarding the relationship between myocardial infarct size and clinical outcomes. The commenter stated that these clinical studies would provide further context to the research regarding the relationship between myocardial infarct size and clinical outcomes and emphasized that this relationship is not dependent on the type of treatment administered. The commenter opined that as long as infarct size is reduced, long-term clinical benefit follows. The commenter maintained that the strong correlation between the scarring of the left ventricle as a consequence of diagnoses of AMI and important long-term clinical outcomes has been well documented in large-scale thrombolytic therapy trials, one of which showed that a 5 percent reduction in medium infarct size was associated with improved clinical outcomes and established the superiority of primary PCI over thrombolysis as the standard-of-care for the treatment of AMI.[159] The commenter indicated that, based on the results of the additional clinical studies, recognizing the significance of the relationship between infarct size and clinical outcomes, additional trials were performed to evaluate the effect of continued infarct size reduction, such as a pooled patient-level analysis to evaluate myocardial infarct size measured within 30 days of STEMI and its relationship to mortality as well as hospitalization for heart failure during and up to 1-year follow up. The commenter stated that one trial demonstrated a highly significant relationship for mortality and hospitalization for heart failure, where every 5 percent increase in infarct size was associated with a 19 percent increase in mortality at 1 year.[160] The commenter further stated that the results of this trial indicated that this relationship was independent of other high-risk clinical and angiographic features in patients with a large infarction, including age, sex, diabetes, hypertension, hyperlipidemia, current smoking, and symptom-to-first device time.[161] The commenter believed that, given this established relationship, the 6.5 percent absolute reduction in median infarct size demonstrated with the use of SSO_2 Therapy in the AMIHOT II trial is clinically meaningful. The commenter concluded that SSO_2 Therapy is the only therapy to date that has demonstrated a significant and clinically meaningful reduction in infarct size beyond that achieved with PCI alone.

Response: We appreciate all of the commenters' input. However, we are concerned whether the additional clinical studies presented regarding the relationship between myocardial infarct size and clinical outcomes can be applied to SSO_2 Therapy and whether the applicant has provided enough information to demonstrate that the reduction of infarct size with use of SSO_2 Therapy is a substantial clinical improvement. We are inviting public comments regarding these concerns.

k. 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 on June 1, 2017 (DEN160043).

Aortic stenosis (AS) is a narrowing of the aortic valve opening. AS restricts blood flow from the left ventricle to the aorta and may also affect the pressure in the left atrium. The most common presenting symptoms of AS include dyspnea on exertion or decreased exercise tolerance, exertional dizziness (presyncope) or syncope and exertional angina. Symptoms experienced by patients who have been diagnosed with AS and normal left ventricular systolic function rarely occur until stenosis is severe (defined as valve area is less than 1.0 cm2, the jet velocity is over 4.0 m/sec, and/or the mean transvalvular gradient is greater than or equal to 40 mmHg).[162] AS is a common valvular disorder in elderly patients. The prevalence of AS increases with age, and some degree of valvular calcification is present in 75 percent of patients who are 85 to 86 years old.[163] TAVR procedures are the standard of care treatment for patients who have been diagnosed with severe AS. Patients undergoing TAVR procedures are often older, frail, and may be affected by multiple comorbidities, implying a significant risk for thromboembolic cerebrovascular events.[164] Embolic ischemic strokes can occur in patients undergoing surgical and interventional cardiovascular procedures, such as stenting (carotid, coronary, peripheral), catheter ablation for atrial fibrillation, endovascular stent grafting, left atrial appendage closure (LAAO), patent formal ovale (PFO) closure, balloon aortic valvuloplasty, surgical valve replacement (SAVR), and TAVR. Clinically overt stroke, or silent ischemic cerebral infarctions, associated with the TAVR procedure, may result from a variety of causes, including mechanical manipulation of instruments or other interventional devices used during the procedure. These mechanical manipulations are caused by, but not limited to, the placement of a relatively large bore delivery catheter in the aortic arch, balloon valvuloplasty, valve positioning, valve re-positioning, valve expansion, and corrective catheter manipulation, as well as use of guidewires and guiding or diagnostic catheters required for proper positioning of the TAVR device. The magnitude and timing of embolic activity resulting from these manipulations was studied by Szeto, et al.,[165] using a transcranial Doppler, and it was found that embolic material is liberated throughout the TAVR procedure with some of the emboli reaching the central nervous system leading to cerebral ischemic infarctions. Some of the cerebral ischemic infarctions lead to neurologic injury and clinically apparent stroke. Szeto, et al., also noted that the rate of

[159] Schömig, A., Kastrati, A., Dirschinger, J., et al., ''Coronary stenting plus platelet glycoprotein IIb/IIIa blockade compared with tissue plasminogen activator in acute myocardial infarction. Stent versus Thrombolysis for Occluded Coronary Arteries in Patients with Acute Myocardial Infarction Study Investigators,'' *New England Journal of Medicine,* 2000, vol. 343(6), pp. 385–91.

[160] Stone, G.W., Selker, H.P., Thiele, H., et al., ''Relationship between infarct size and outcomes following primary PCI,'' *JACC,* 2016, vol. 67(14), pp. 1674–83.

[161] Ibid.

[162] Otto, C., Gaasch, W., ''Clinical manifestations and diagnosis of aortic stenosis in adults,'' In S. Yeon (Ed.), 2016, Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-aortic-stenosis-in-adults.*

[163] Lindroos, M., et al., ''Prevalence of aortic valve abnormalities in the elderly: An echocardiographic study of a random population sample,'' *J Am Coll Cardio,* 1993, vol. 21(5), pp. 1220–1225.

[164] Giustino, G., et al., ''Neurological Outcomes With Embolic Protection Devices in Patients Undergoing Transcatheter Aortic Valve Replacement,'' *J Am Coll Cardio,* CARDIOVASCULAR INTERVENTIONS, 2016, vol. 9(20).

[165] Szeto, W.Y., et al., ''Cerebral Embolic Exposure During Transfemoral and Transapical Transcatheter Aortic Valve Replacement,'' *J Card Surg,* 2011, vol. 26, pp. 348–354.

silent ischemic cerebral infarctions following TAVR procedures is estimated to be between 68 and 91 percent.[166] [167]

The TAVR procedure is a minimally invasive procedure that does not involve open heart surgery. During a TAVR procedure the prosthetic aortic valve is placed within the diseased native valve. The prosthetic valve then becomes the functioning aortic valve. As previously outlined, stroke is one of the risks associated with TAVR procedures. According to the applicant, the risk of stroke is highest in the early post-procedure period and, as previously outlined, is likely due to mechanical factors occurring during the TAVR procedure.[168] Emboli can be generated as wire-guided devices are manipulated within atherosclerotic vessels, or when calcified valve leaflets are traversed and then crushed during valvuloplasty and subsequent valve deployment.[169] Stroke rates in patients evaluated 30 days after TAVR procedures range from 1.0 percent to 9.6 percent,[170] and have been associated with increased mortality. Additionally, new ''silent infarcts,'' assessed via diffusion-weighted magnetic resonance imaging (DW–MRI), have been found in a majority of patients after TAVR procedures.[171]

As stated earlier, the De Novo request for the Sentinel® Cerebral Protection System was granted on June 1, 2017. The FDA concluded that this device should be classified into Class II (moderate risk). Effective October 1, 2016, ICD–10–PCS Section ''X'' code X2A5312 (Cerebral embolic filtration, dual filter in innominate artery and left common carotid artery, percutaneous approach) was approved to identify cases involving TAVR procedures using the Sentinel® Cerebral Protection System.

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 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, the Sentinel® Cerebral Protection System device is inserted at the beginning of the TAVR procedure, via a small tube inserted through a puncture in the right wrist. Next, using a minimally invasive catheter, two small filters are placed in the brachiocephalic and left common carotid arteries. The filters collect debris, preventing it from becoming emboli, which can travel to the brain. These emboli, if left uncaptured, can cause cerebral ischemic lesions, often referred to as silent ischemic cerebral infarctions, potentially leading to cognitive decline or clinically overt stroke. At the completion of the TAVR procedure, the filters, along with the collected debris, are removed. The applicant stated that there are no other similar products for commercial sale available in the United States for cerebral protection during TAVR procedures. Two neuroprotection devices, the Triguard™ Cerebral Protection Device (Keystone Heart, Herzliya Pituach, Israel) and the Embrella Embolic Deflector™ System (Edwards Lifesciences, Irvine, CA) are used in Europe. These devices work by deflecting embolic debris distally, rather than capturing and removing debris with filters.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, as stated earlier, the Sentinel® Cerebral Protection System is an EP device used to capture and remove thrombus and debris while performing TAVR procedures. Therefore, potential cases representing patients who may be eligible for treatment involving this device would map to the same MS–DRGs as cases involving TAVR procedures.

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, this technology will be used to treat patients who have been diagnosed with severe aortic valve stenosis who are eligible for a TAVR procedure. The applicant asserted that there are currently no approved alternative treatment options for cerebral protection during TAVR procedures, and the Sentinel® Cerebral Protection System is the first and only embolic protection device for use during TAVR procedures and, therefore, meets the newness criterion. The applicant also asserted that the device meets the newness criterion, as evidenced by the FDA's granting of the De Novo request and there was no predicate device.

Based on the above, it appears that the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies. We are inviting public comments on whether the Sentinel® Cerebral Protection System is substantially similar to any existing technology and whether it meets the newness criterion.

The applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2016 MedPAR file for cases with the following ICD–10–CM procedure codes to identify cases involving TAVR procedures, which are potential cases representing patients who may be eligible for treatment involving use of the Sentinel® Cerebral Protection System: 02RF37Z (Replacement of aortic valve with autologous tissue substitute, percutaneous approach); 02RF38Z (Replacement of aortic valve with zooplastic tissue, percutaneous approach); 02RF3JZ (Replacement of aortic valve with synthetic substitute, percutaneous approach); 02RF3KZ (Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach); 02RF37H (Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach); 02RF38H (Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach); 02RF3JH (Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach); and 02RF3KH (Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach). This process resulted in 26,012 potential cases. The applicant limited its search to MS–DRG 266 (Endovascular Cardiac Valve Replacement with MCC) and MS–DRG 267 (Endovascular Cardiac Valve Replacement without MCC) because these two MS–DRGs accounted for 97.4 percent of the total cases identified.

Using the 26,012 identified cases, the applicant determined that the average unstandardized case-weighted charge per case was $211,261. No charges were removed for the prior technology because the device is used to capture

[166] Gupta, A., Giambrone, A.E., Gialdini, G., et al., ''Silent brain infarction and risk of future stroke: A systematic review and meta-analysis,'' *Stroke,* 2016, vol. 47, pp. 719–25.

[167] Mokin, M., Zivadinov, R., Dwyer, M.G., Lazar, R.M., Hopkins, L.N., Siddiqui, A.H., ''Transcatheter aortic valve replacement: perioperative stroke and beyond,'' *Expert Rev Neurother,* 2017, vol. 17, pp. 327–34.

[168] Nombela-Franco, L., et al., ''Timing, predictive factors, and prognostic value of cerebrovascular events in a large cohort of patients undergoing transcatheter aortic valve implantation,'' *Circulation,* 2012, vol. 126(25), pp. 3041–53.

[169] Freeman, M., et al., ''Cerebral events and protection during transcatheter aortic valve replacement,'' *Catheterization and Cardiovascular Interventions,* 2014, vol. 84(6), pp. 885–896.

[170] Haussig, S., Linke, A., ''Transcatheter aortic valve replacement indications should be expanded to lower-risk and younger patients,'' *Circulation,* 2014. vol. 130(25), pp. 2321–31.

[171] Kahlert, P., et al., ''Silent and apparent cerebral ischemia after percutaneous transfemoral aortic valve implantation: a diffusion-weighted magnetic resonance imaging study,'' *Circulation,* 2010, vol. 121(7), pp. 870–8.

and remove thrombus and debris while performing TAVR procedures. The applicant then standardized the charges, but did not inflate the charges. The applicant then added charges for the new technology to the average case-weighted standardized charges per case by taking the cost of the device and dividing the amount by the CCR of 0.332 for implantable devices from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38103). The applicant calculated a final inflated average case-weighted standardized charge per case of $187,707 and a Table 10 average case-weighted threshold amount of $170,503. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. We are inviting public comments on whether the Sentinel® Cerebral Protection System meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the Sentinel® Cerebral Protection System represents a substantial clinical improvement over existing technologies because it is the first and only cerebral embolic protection device commercially available in the United States for use during TAVR procedures. The applicant stated that the data below shows that the Sentinel® Cerebral Protection System effectively captures brain bound embolic debris and significantly improves clinical outcomes (that is, stroke) beyond the current standard of care, that is, TAVR procedures with no embolic protection.

The applicant provided the results of four key studies: (1) The SENTINEL® study [172] conducted by Claret Medical, Inc.; (2) the CLEAN-TAVI trial; [173] (3) the Ulm real-world registry; [174] and (4) the MISTRAL–C study.[175]

The applicant reported that the SENTINEL® study was a prospective, single blind, multi-center, randomized study using the Sentinel® Cerebral Protection System which enrolled patients who had been diagnosed with severe symptomatic calcified native aortic valve stenosis indicated for a TAVR procedure. A total of 363 patients at 19 centers in the United States and Germany were randomized across 3 arms (Safety, Test, and Control) in a 1:1:1 fashion. According to the applicant, evaluations performed for patients in each arm were as follows:

- Safety Arm patients who underwent a TAVR procedure involving the Sentinel® Cerebral Protection System—Patients enrolled in this arm of the study received safety follow-up at discharge, at 30 days and 90 days post-procedure; and neurological evaluation at baseline, discharge, 30 days and 90 days (only in the case of a stroke experienced less than or equal to 30 days) post-procedure. The Safety Arm patients did not undergo MRI or neurocognitive assessments.
- Test Arm patients who underwent a TAVR procedure involving the Sentinel® Cerebral Protection System—Patients enrolled in this arm of the study underwent safety follow-up at discharge, at 30 days and 90 days post-procedure; MRI assessment for efficacy at baseline, 2 to 7 days and 30 days post-procedure; neurological evaluation at baseline, discharge, 30 days and 90 days (only in the case of a stroke experienced less than or equal to 30 days) post-procedure; neurocognitive evaluation at baseline, 2 to 7 days (optional), 30 days and 90 days post-procedure; Quality of Life assessment at baseline, 30 days and 90 days; and histopathological evaluation of debris captured in the Sentinel® Cerebral Protection System's device filters.
- Control Arm patients who underwent a TAVR procedure only—Patients enrolled in this arm of the study underwent safety follow-up at discharge, at 30 days and 90 days post-procedure; MRI assessment for efficacy at baseline, 2 to 7 days and 30 days post-procedure; neurological evaluation at baseline, discharge, 30 days and 90 days (only in the case of a stroke experienced less than or equal to 30 days) post-procedure; neurocognitive evaluation at baseline, 2 to 7 days (optional), 30 days and 90 days post-procedure; and Quality of Life assessment at baseline, 30 days and 90 days.

The primary safety endpoint was occurrence of major adverse cardiac and cerebrovascular events (MACCE) at 30 days compared with a historical performance goal. MACCE was defined as follows: All causes of death; all strokes (disabling and nondisabling, Valve Academic Research Consortium-2 (VARC–2)); and acute kidney injury (stage 3, VARC–2). The point estimate for the historical performance goal for the primary safety endpoint at 30 days post-TAVR procedure was derived from a review of published reports of 30-day TAVR procedure outcomes. The VARC–2 established an independent collaboration between academic research organizations and specialty societies (cardiology and cardiac surgery) in the United States and Europe to create consistent endpoint definitions and consensus recommendations for implementation in TAVR procedure clinical research.[176]

The applicant reported that results of the SENTINEL® study demonstrated the following:

- The rate of MACCE was numerically lower than the control arm, 7.3 percent versus 9.9 percent, but was not statistically significant from that of the control group (p = 0.41).
- New lesion volume was 178.0 mm^3 in control patients and 102.8 mm^3 in the Sentinel® Cerebral Protection System device arm (p = 0.33). A post-hoc multi-variable analysis identified preexisting lesion volume and valve type as predictors of new lesion volume.
- Strokes experienced at 30 days were 9.1 percent in control patients and 5.6 percent in patients treated with the Sentinel® Cerebral Protection System devices (p = 0.25). Neurocognitive function was similar in control patients and patients treated with the Sentinel® Cerebral Protection System devices, but there was a correlation between lesion volume and neurocognitive decline (p = 0.0022).
- Debris was found within filters in 99 percent of patients and included thrombus, calcification, valve tissue, artery wall, and foreign material.
- The applicant also noted that the post-hoc analysis of this data demonstrated that there was a 63 percent reduction in 72-hour stroke rate (compared to control), p = 0.05.

According to the applicant, the CLEAN–TAVI (Claret Embolic Protection and TAVI) trial, was a small, randomized, double-blind, controlled trial. The trial consisted of 100 patients assigned to either EP (n = 50) with the Claret Medical, Inc. device (the Sentinel® Cerebral Protection System) or to no EP (n = 50). Patients were all

[172] Kapadia, S., Kodali, S., Makkar, R., et al., ''Protection against cerebral embolism during transcatheter aortic valve replacement,'' *JACC,* 2017, vol. 69(4), pp. 367–377.

[173] Haussig, S., Mangner, N., Dwyer, M.G., et al., ''Effect of a Cerebral Protection Device on Brain Lesions Following Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Stenosis: The CLEAN–TAVI Randomized Clinical Trial,'' *JAMA,* 2016, vol. 316, pp. 592–601.

[174] Seeger, J., et al., ''Cerebral Embolic Protection During Transfemoral Aortic Valve Replacement Significantly Reduces Death and Stroke Compared With Unprotected Procedures,'' *JACC Cardiovasc Interv,* 2017, in press.

[175] Mieghem, Van, et al., ''Filter-based cerebral embolic protection with transcatheter aortic valve implantation: the randomized MISTRAL–C trial,'' *Eurointervention,* 2016, vol. 12(4), pp. 499–507.

[176] Leon, M.B., Piazza, N., Nikolsky, E., et al., ''Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium,'' *European Heart Journal,* 2011, vol. 32(2), pp. 205–217, doi:10.1093/eurheartj/ehq406.

treated with femoral access and self-expandable (SE) devices. The study endpoint was the number of brain lesions at 2 days post-procedure versus baseline. Patients were evaluated with DW-MRI at 2 and 7 days post-TAVR procedure. The mean age of patients was 80 years old; 43 percent were male. The study results showed that patients treated with the Sentinel® Cerebral Protection System had a lower number of new lesions (4.00) than patients in the control group (10.0); (p<0.001).

According to the applicant, the single-center Ulm study, a large propensity matched trial, with 802 consecutive patients, occurred at the University of Ulm between 2014 and 2016. The first 522 patients (65.1 percent of patients) underwent a TAVR procedure without EPs, and the subsequent 280 patients (34.9 percent of patients) underwent a TAVR procedure with EP involving the Sentinel® Cerebral Protection System. For both arms of the study, a TAVR procedure was performed in identical settings except without cerebral EP, and neurological follow-up was performed within 7 days post-procedure. The primary endpoint was a composite of all-cause mortality or all-stroke according to the VARC–2 criteria within 7 days. The authors who documented the study noted the following:

- Patient baseline characteristics and aortic valve parameters were similar between groups, that both filters of the device were successfully positioned in 280 patients, all neurological follow-up was completed by the 7th post-procedure date, and that propensity score matching was performed to account for possible confounders.
- Results indicated a decreased rate of disabling and nondisabling stroke at 7 days post-procedure was seen in those patients who were treated with the Sentinel® Cerebral Protection System device versus control patients (1.6 percent versus 4.6 percent, p = 0.03).
- At 48 hours, stroke rates were lower with patients treated with the Sentinel® Cerebral Protection System device versus control patients (1.1 percent versus 3.6 percent, p = 0.03).
- In multi-variate analysis, TAVR procedures performed without the use of a EP device was found to be an independent predictor of stroke within 7 days (p = 0.04).

The aim of the MISTRAL–C study was to determine if the Sentinel® Cerebral Protection System affects new brain lesions and neurocognitive performance after TAVR procedures. The study was designed as a multi-center, double-blind, randomized trial enrolling patients who were diagnosed with symptomatic severe aortic stenosis and 1:1 randomization to TAVI patients treated with or without the Sentinel® Cerebral Protection System. From January 2013 to August 2015, 65 patients were enrolled in the study. Patients ranged in age from 77 years old to 86 years old, 15 (47 percent) were female and 17 (53 percent) were male patients randomized to the Sentinel® Cerebral Protection System group and 16 (49 percent) were female and 17 (51 percent) were male patients randomized to the control group. There were 3 mortalities between 5 days and 6 months post-procedure for the Sentinel® Cerebral Protection System group. There were no strokes reported for the Sentinel® Cerebral Protection System group. There were 7 mortalities between 5 days and 6 months post-procedure for the control group. There were 2 strokes reported for the control group. Patients underwent DW–MRI and neurological examination, including neurocognitive testing 1 day before and 5 to 7 days after TAVI. Follow-up DW–MRI and neurocognitive testing was completed in 57 percent of TAVI patients treated with the Sentinel® Cerebral Protection System and 80 percent for the group of TAVI patients treated without the Sentinel® Cerebral Protection System. New brain lesions were found in 78 percent of the patients with follow-up MRI. According to the applicant, patients treated with the Sentinel® Cerebral Protection System had numerically fewer new lesions and a smaller total lesion volume (95 mm3 versus 197 mm3). Overall, 27 percent of the patients treated with the Sentinel® Cerebral Protection System and 13 percent of the patients treated in the control group had no new lesions. Ten or more new brain lesions were found only in the patients treated in the control group (20 percent in the control group versus 0 percent in the Sentinel® Cerebral Protection System group, p = 0.03). Neurocognitive deterioration was present in 4 percent of the patients treated with the Sentinel® Cerebral Protection System versus 27 percent of the patients treated without (p=0.017). The filters captured debris in all of the patients treated with Sentinel® Cerebral Protection System device.

In the Ulm study, the primary outcome was a composite of all-cause mortality or stroke at 7 days, and occurred in 2.1 percent of the Sentinel® Cerebral Protection System group versus 6.8 percent of the control group (p = 0.01, number needed to treat (NNT) = 21). Use of the Sentinel® Cerebral Protection System device was associated with a 2.2 percent absolute risk reduction in mortality with NNT 45. Composite endpoint of major adverse cardiac and cerebrovascular events (MACCE) was found in 2.1 percent of those patients undergoing a TAVR procedure with the use of the Sentinel® Cerebral Protection System device versus 7.9 percent in the control group (p = 0.01). Similar but statistically nonsignificant trends were found in the SENTINEL® study, with rate of MACCE of 7.3 percent in the Sentinel® Cerebral Protection System group versus 9.9 percent in the control group (p = 0.41).

The applicant reported that the four studies discussed above that evaluated the Sentinel® Cerebral Protection System device have limitations because they are either small, nonrandomized and/or had significant loss to follow-up. A meta-analysis of EP device studies, the majority of which included use of the Sentinel® Cerebral Protection System device, found that use of cerebral EP devices was associated with a nonsignificant reduction in stroke and death.[177]

We are concerned that the use of cerebral protection devices may not be associated with a significant reduction in stroke and death. We note that the SENTINEL® study, although a randomized study, did not meet its primary endpoint, as illustrated by nonstatistically significant reduction in new lesion volume on MRI or nondisabling strokes within 30 days (5.6 percent stroke rate in the Sentinel® Cerebral Protection System device group versus a 9.1 percent stroke rate in the control group at 30 days; p = 0.25). We also note that only with a post-hoc analysis of the SENTINEL® study data were promising trends noted, where the device use was associated with a 63 percent reduction in stroke events at 72 hours (p = 0.05). Additionally, although there was a statistically significant difference between the patients treated with and without cerebral embolic protection in the composite of all-cause mortality or stroke at 7 days, the Ulm study was a nonrandomized study and propensity matching was performed during analyses. We are concerned that studies involving the Sentinel® Cerebral Protection System may be inconclusive regarding whether the device represents a substantial clinical improvement for patients undergoing TAVR procedures. We also are concerned that the SENTINEL® studies did not show a substantial decrease in neurological

[177] Giustino, G., et al., ''Neurological Outcomes With Embolic Protection Devices in Patients Undergoing Transcatheter Aortic Valve Replacement,'' *Journal of the American College of Cardiology: Cardiovascular Interventions,* 2016, vol. 9(20), pp. 2124–2133.

complications for patients undergoing TAVR procedures. We are inviting public comments on whether the Sentinel® Cerebral Protection System meets the substantial clinical improvement criterion.

Below we summarize and respond to a written public comment we received regarding the Sentinel® Cerebral Protection System during the open comment period in response to the New Technology Town Hall meeting notice published in the **Federal Register**.

Comment: One commenter noted that the TriGUARD device, a similar device to the Sentinel® Cerebral Protection System device, has been commercially available throughout Europe and its member countries, including the United Kingdom since June 29, 2013. The commenter indicated that the TriGUARD device received its Israel Medical Device Registration and Approval (AMAR) on November 5, 2015. The commenter asserted that because the Sentinel® Cerebral Protection System is the first and only cerebral EP device commercially available in the United States for use during TAVR procedures it represents a substantial clinical improvement over currently available and existing technologies.

Response: We appreciate the information provided by the commenter. We will take this information into consideration when deciding whether to approve new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2019.

l. AZEDRA® (Ultratrace® Iobenguane Iodine-131) Solution

Progenics Pharmaceuticals, Inc. submitted an application for new technology add-on payments for AZEDRA® (Ultratrace® iobenguane Iodine-131) for FY 2019. 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. AZEDRA® contains a small molecule ligand consisting of meta-iodobenzylguanidine (MIBG) and ^{131}Iodine (^{131}I) (hereafter referred to as ''^{131}I–MIBG''). The applicant noted that iobenguane Iodine-131 is also known as ^{131}I–MIBG).

The applicant reported in its application that pheochromocytomas and paragangliomas are rare tumors with an incidence of approximately 2 to 8 people per million per year.[178] [179] Both tumors are catecholamine-secreting neuroendocrine tumors, with pheochromocytomas being the more common of the two and comprising 80 to 85 percent of cases. While 10 percent of pheochromocytomas are malignant, whereby ''malignant'' is defined by the World Health Organization (WHO) as ''the presence of distant metastases,'' paragangliomas have a malignancy frequency of 25 percent.[180] [181] Approximately one-half of malignant tumors are pronounced at diagnosis, while other malignant tumors develop slowly within 5 years.[182] Pheochromocytomas and paragangliomas tend to be indistinguishable at the cellular level and frequently at the clinical level. For example catecholamine-secreting paragangliomas often present clinically like pheochromocytomas with hypertension, episodic headache, sweating, tremor, and forceful palpitations.[183] Although pheochromocytomas and paragangliomas can share overlapping histopathology, epidemiology, and molecular pathobiology characteristics, there are differences between these two neuroendocrine tumors in clinical behavior, aggressiveness and metastatic potential, biochemical findings and association with inherited genetic syndrome differences, highlighting the importance of distinguishing between the presence of malignant pheochromocytoma and the presence of malignant paraganglioma. At this time, there is no curative treatment for malignant pheochromocytomas and paragangliomas. Successful management of these malignancies requires a multidisciplinary approach of decreasing tumor burden, controlling endocrine activity, and treating debilitating symptoms. According to the applicant, decreasing metastatic tumor burden would address the leading cause of mortality in this patient population, where the 5-year survival rate is 50 percent for patients with untreated malignant pheochromocytomas and paragangliomas.[184] The applicant stated that controlling catecholamine hypersecretion (for example, severe paroxysmal or sustained hypertension, palpitations and arrhythmias) would also mean decreasing morbidity associated with hypertension (for example, risk of stroke, myocardial infarction and renal failure), and begin to address the 30-percent cardiovascular mortality rate associated with malignant pheochromocytomas and paragangliomas.

The applicant reported that, at this time, controlling catecholamine activity in pheochromocytomas and paragangliomas is medically achieved with administration of combined alpha and beta-adrenergic blockade, and surgically with tumor tissue reduction. Because there is no curative treatment for malignant pheochromocytomas and paragangliomas, resecting both primary and metastatic lesions whenever possible to decrease tumor burden [185] provides a methodology for controlling catecholamine activity and lowering cardiovascular mortality risk. Besides surgical removal of tumor tissue for lowering tumor burden, there are other treatment options that depend upon tumor type (that is, pheochromocytoma tumors versus paraganglioma tumors), anatomic location, and the number and size of the metastatic tumors. Currently, these treatment options include: (1) Radiation therapy; (2) nonsurgical local ablative therapy with radiofrequency ablation, cryoablation, and percutaneous ethanol injection; (3) transarterial chemoembolization for liver metastases; and (4) radionuclide therapy using metaiodobenzylguanidine (MIBG) or somatostatin. Regardless of the method to reduce local tumor burden, periprocedural medical care is needed to prevent massive catecholamine secretion and hypertensive crisis.[186]

[178] Beard, C.M., Sheps, S.G., Kurland, L.T., Carney, J.A., Lie, J.T., ''Occurrence of pheochromocytoma in Rochester, Minnesota'', pp. 1950–1979.

[179] Stenström, G., Svärdsudd, K., ''Pheochromocytoma in Sweden 1958–1981. An analysis of the National Cancer Registry Data,'' *Acta Medica Scandinavica,* 1986, vol. 220(3), pp. 225–232.

[180] Fishbein, Lauren, ''Pheochromocytoma and Paraganglioma,'' *Hematology/Oncology Clinics* 30, no. 1, 2016, pp. 135–150.

[181] Lloyd, R.V., Osamura, R.Y., Klöppel, G., & Rosai, J. (2017). World Health Organization (WHO) Classification of Tumours of Endocrine Organs. Lyon, France: International Agency for Research on Center (IARC).

[182] Kantorovich, Vitaly, and Karel Pacak. ''Pheochromocytoma and paraganglioma.'' *Progress in Brain Research.,* 2010, vol. 182, pp. 343–373.

[183] Carty, S.E., Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

[184] Kantorovich, Vitaly, and Karel Pacak. ''Pheochromocytoma and paraganglioma.'' *Progress in Brain Research.,* 2010, vol. 182, pp. 343–373.

[185] Noda, T., Nagano, H., Miyamoto, A., et al., ''Successful outcome after resection of liver metastasis arising from an extraadrenal retroperitoneal paraganglioma that appeared 9 years after surgical excision of the primary lesion,'' *Int J Clin Oncol,* 2009, vol. 14, pp. 473.

[186] Carty, S.E., Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.*

Continued

The applicant stated that AZEDRA® specifically targets neuroendocrine tumors arising from chromaffin cells of the adrenal medulla (in the case of pheochromocytomas) and from neuroendocrine cells of the extra-adrenal autonomic paraganglia (in the case of paragangliomas).[187] According to the applicant, AZEDRA® is a more consistent form of ^{131}I-MIBG compared to compounded formulations of ^{131}I-MIBG that are not currently approved by the FDA. If approved by the FDA, the applicant asserted that AZEDRA® would be the only drug indicated for use in the treatment of patients, who if left untreated, experience debilitating clinical symptoms and high mortality rates from iobenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors.

Among local tumor tissue reduction options, use of external beam radiation therapy (ERBT) at doses greater than 40 Gy can provide local pheochromocytoma and paraganglioma tumor control and relief of symptoms for tumors at a variety of sites, including the soft tissues of the skull base and neck, abdomen, and thorax, as well as painful bone metastases.[188] However, the applicant stated that ERBT irradiated tissues are unresponsive to subsequent treatment with ^{131}I-MIBG radionuclide.[189] MIBG was initially used for the imaging of paragangliomas and pheochromocytomas because of its similarity to noradrenaline, which is taken up by chromaffin cells. Conventional MIBG used in imaging expanded to off-label compassionate use in patients who had been diagnosed with malignant pheochromocytomas and paragangliomas. Because ^{131}I-MIBG is sequestered within pheochromocytoma and paraganglioma tumors, subsequent malignant cell death occurs from radioactivity. Approximately 50 percent of tumors are eligible for ^{131}I-MIBG therapy based on having MIBG uptake with diagnostic imaging. According to the applicant, despite uptake by tumors, studies have also found that ^{131}I-MIBG therapy has been limited by total radiation dose, hematologic side effects, and hypertension. While the pathophysiology of total radiation dose and hematologic side effects are more readily understandable, hypertension is believed to be precipitated by large quantities of non-iodinated MIBG or ''cold'' MIBG being introduced along with radioactive ^{131}I-MIBG therapy.[190] The ''cold'' MIBG blocks synaptic reuptake of norepinephrine, which can lead to tachycardia and paroxysmal hypertension within the first 24 hours, the majority of which occur within 30 minutes of administration and can be dose-limiting.[191]

The applicant asserted that its new proprietary manufacturing process called Ultratrace® allows AZEDRA® to be manufactured without the inclusion of unlabeled or ''cold'' MIBG in the final formulation. The applicant also noted that targeted radionuclide MIBG therapy to reduce tumor burden is one of two treatments that have been studied the most. The other treatment is cytotoxic chemotherapy and, specifically, Carboplatin, Vincristine, and Dacarbazine (CVD). The applicant stated that cytotoxic chemotherapy is an option for patients who experience symptoms with rapidly progressive, non-resectable, high tumor burden, or that cytoxic chemotherapy is another option for a large number of metatstatic bone lesions.[192] According to the applicant, CVD was believed to have an effect on malignant pheochromocytomas and paragangliomas due to the embryonic origin being similar to neuroblastomas. The response rates to CVD have been variable between 25 percent and 50 percent.[193] [194] These patients experience side effects consistent with chemotherapeutic treatment with CVD, with the added concern of the precipitation of hormonal complications such as hypertensive crisis, thereby requiring close monitoring during cytotoxic chemotherapy.[195] According to the applicant, use of CVD relative to other tumor burden reduction options is not an ideal treatment because of nearly 100 percent recurrence rates, and the need for chemotherapy cycles to be continually readministered at the risk of increased systemic toxicities and eventual development of resistance. Finally, there is a subgroup of patients that are asymptomatic and have slower progressing tumors where frequent follow-up is an option for care.[196] Therefore, the applicant believed that AZEDRA® offers cytotoxic radioactive therapy for the anticipated indicated population that avoids harmful side effects that typically result from use of low-specific activity products.

The applicant reported that the anticipated and recommended AZEDRA® dosage and frequency for patients receiving treatment involving ^{131}I-MIBG therapy for a diagnosis of avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors is:

- Dosimetric Dosing—5 to 6 micro curies (mCi) (185 to 222 MBq) for a patient weighing more than or equal to 50 kg, and 0.1 mCi/kg (3.7 MBq/kg) for patients weighing less than 50 kg. Each recommended dosimetric dose is administered as an IV injection.
- Therapeutic Dosing—500 mCi (18.5 GBq) for patients weighing more than 62.5 kg, and 8 mCi/kg (296 MBq/kg) for patients weighing less than or equal to 62.5 kg. Therapeutic doses are administered by IV infusion, in ~50 mL over a period of ~30 minutes (100 mL/hour), administered approximately 90 days apart.

With respect to the newness criterion, the applicant indicated that FDA granted Orphan Drug designation for AZEDRA® on January 18, 2006, followed by Fast Track designation on March 8, 2006, and Breakthrough Therapy designation on July 26, 2015. The applicant's New Drug Application (NDA) proceeded on a rolling basis, and was completed on November 2, 2017.

Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

[187] Ibid.

[188] Ibid.

[189] Fitzgerald, P.A., Goldsby, R.E., Huberty, J.P., et al., ''Malignant pheochromocytomas and paragangliomas: a phase II study of therapy with high-dose 131I-metaiodobenzylguanidine (131I-MIBG),'' *Ann N Y Acad Sci,* 2006, vol. 1073, pp. 465.

[190] Loh, K.C., Fitzgerald, P.A., Matthay, K.K., Yeo, P.P., Price, D.C., ''The treatment of malignant pheochromocytoma with iodine-131 metaiodobenzylguanidine (^{131}I-MIBG): a comprehensive review of 116 reported patients,'' *J Endocrinol Invest,* 1997, vol. 20(11), pp. 648–658.

[191] Gonias, S, et al., ''Phase II Study of High-Dose [^{131}I]Metaiodobenzylguanidine Therapy for Patients With Metastatic Pheochromocytoma and Paraganglioma,'' *J of Clin Onc,* July 27, 2009.

[192] Carty, S.E., Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

[193] Niemeijer, N.D., Alblas, G., Hulsteijn, L.T., Dekkers, O.M. and Corssmit, E.P.M., ''Chemotherapy with cyclophosphamide, vincristine and dacarbazine for malignant paraganglioma and pheochromocytoma: systematic review and meta-analysis,'' *Clinical endocrinology,* 2014, vol 81(5), pp. 642–651.

[194] Ayala-Ramirez, Montserrat, et al., ''Clinical Benefits of Systemic Chemotherapy for Patients with Metastatic Pheochromocytomas or Sympathetic Extra-Adrenal Paragangliomas: Insights from the Largest Single Institutional Experience,'' *Cancer,* 2012, vol. 118(11), pp. 2804–2812.

[195] Wu, L.T., Dicpinigaitis, P., Bruckner, H., et al., ''Hypertensive crises induced by treatment of malignant pheochromocytoma with a combination of cyclophosphamide, vincristine, and dacarbazine,'' *Med Pediatr Oncol,* 1994, vol. 22(6), pp. 389–392.

[196] Carty, S.E., Young, W.F., Elfky, A., ''Paraganglioma and pheochromocytoma: Management of malignant disease,'' *UpToDate.* Available at: *https://www.uptodate.com/contents/paraganglioma-and-pheochromocytoma-management-of-malignant-disease.*

However, at the time of the development of this proposed rule, the applicant indicated that it had not yet received FDA approval for the indicated use of AZEDRA®. The applicant stated that it anticipates FDA approval by June 30, 2018. Currently, there are no approved ICD–10–PCS procedure codes to uniquely identify procedures involving the administration of AZEDRA®.

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 purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action, the applicant stated that while AZEDRA® and low-specific activity conventional I-131 MIBG both target the same transporter sites on the tumor cell surface, the therapies' safety and efficacy outcomes are different. These differences in outcomes are because AZEDRA® is manufactured using the proprietary Ultratrace® technology, which maximizes the molecules that carry the tumoricidal component (I-131 MIBG, the warhead) and minimizes the extraneous unlabeled component (MIBG, free ligands), which could cause cardiovascular side effects. Therefore, according to the applicant, AZEDRA® is designed to increase efficacy and decrease safety risks, whereas conventional I-131 MIBG uses existing technologies and results in a product that overwhelms the normal reuptake system with excess free ligands, which leads to safety issues as well as decreasing the probability of the warhead binding to the tumor cells.

With regard to the second criterion, whether a product is assigned to the same or a different DRG, the applicant noted that there are no specific MS–DRGs for the assignment of cases involving the treatment of patients who have been diagnosed with pheochromocytoma and paraganglioma. We believe that potential cases representing patients who may be eligible for treatment involving the administration of AZEDRA® would be assigned to the same MS–DRGs as cases representing patients who receive treatment for obenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma. We also refer readers to the cost criterion discussion below, which includes the applicant's list of the MS–DRGs that potential cases involving treatment with the administration of AZEDRA® most likely would map.

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, if approved, AZEDRA® would be the only FDA-approved drug indicated for use in the treatment of patients who have been diagnosed with malignant pheochromocytoma and paraganglioma tumors that avidly take up ^{131}I-MIBG and are recurrent and/or unresectable. The applicant stated that these patients face serious mortality and morbidity risks if left untreated, as well as potentially suffer from side effects if treated by available off-label therapies.

The applicant also contended that AZEDRA® can be distinguished from other currently available treatments because it potentially provides the following advantages:

- AZEDRA® will have a very limited impact on normal norepinephrine reuptake due to the negligible amount of unlabeled MIBG present in the dose. Therefore, AZEDRA® is expected to pose a much lower risk of acute drug-induced hypertension.
- There is minimal unlabeled MIBG to compete for the norepinephrine transporter binding sites in the tumor, resulting in more effective delivery of radioactivity.
- Current off-label therapeutic use of ^{131}I is compounded by individual pharmacies with varied quality and conformance standards.
- Because of its higher specific activity (the activity of a given radioisotope per unit mass), AZEDRA® infusion times are significantly shorter than conventional ^{131}I administrations.

Therefore, with these potential advantages, the applicant maintained that AZEDRA® represents an effective option for the treatment of patients who have been diagnosed with malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, where there is a clear, unmet medical need.

For the reasons cited earlier, the applicant believed that AZEDRA® is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. We are inviting public comments on whether AZEDRA® is substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion.

The applicant reported that it conducted an analysis using FY 2015 MedPAR data to demonstrate that AZEDRA® meets the cost criterion. The applicant searched for potential cases representing patients who may be eligible for treatment involving AZEDRA® that had one of the following ICD–9–CM diagnosis codes (which the applicant believed is indicative of diagnosis appropriate for treatment involving AZEDRA®): 194.0 (Malignant neoplasm of adrenal gland), 194.6 (Malignant neoplasm of aortic body and other paraganglia), 209.29 (Malignant carcinoid tumor of other sites), 209.30 (Malignant poorly differentiated neuroendocrine carcinoma, any site), 227.0 (Benign neoplasm of adrenal gland), 237.3 (Neoplasm of uncertain behavior of paraganglia)—in combination with one of the following ICD–9–CM procedure codes describing the administration of a radiopharmaceutical: 00.15 (High-dose infusion interleukin-2); 92.20 (Infusion of liquid brachytherapy radioisotope); 92.23 (Radioisotopic teleradiotherapy); 92.27 (Implantation or insertion of radioactive elements); 92.28 (Injection or instillation of radioisotopes). The applicant stated that the combination of these diagnosis and procedure codes in this process was intended to identify potential cases representing patients who had been diagnosed with a correlating condition relating to AZEDRA®'s intended treatment use and who had received subsequent treatment with a predecessor radiopharmaceutical therapy (such as, for example, a potential off-label use of conventional I-131 MIBG therapy) for malignant and/or recurrent pheochromocytoma and paraganglioma tumors. The applicant reported that the potential cases used for the cost analysis mapped to MS–DRGs 054 and 055 (Nervous System Neoplasms with and without MCC, respectively), MS–DRG 271 (Other Major Cardiovascular Procedures with CC), MS–DRG 436 (Malignancy of Hepatobiliary System or Pancreas with CC), MS–DRG 827 (Myeloproliferated Disorder or Poorly Differentiated Neoplasm with Major O.R. Procedure with CC), and MS–DRG 843 (Other Myeloproliferated Disorder or Poorly Differentiated Neoplasm Diagnosis with MCC). Due to patient privacy concerns, the applicant stated that the MedPAR data did not identify the exact number of cases assigned to the six identified MS–DRGs. For purposes of its analysis, the applicant assumed an equal distribution between these six MS–DRGs. The applicant noted in its application that potential cases that may be eligible for treatment involving the administration of AZEDRA® would typically map to other MS–DRGs such as MS–DRGs 643, 644, and 645 (Endocrine Disorders with MCC, with CC, and without CC/MCC, respectively), and MS–DRG 849 (Radiotherapy).

However, because data were not available for these MS–DRGs they were not included in the analysis. Using the identified cases, the applicant determined that the average unstandardized case-weighted charge per case was $95,472. The applicant used a 3-year inflation factor of 1.14359 (a yearly inflation factor of 1.04574 applied over 3 years), based on the FY 2018 IPPS/LTCH PPS final rule (82 FR 38527), to inflate the charges from FY 2015 to FY 2018. The applicant determined an inflated average case-weighted standardized charge per case of $103,833. Because the price of AZEDRA® has yet to be determined, the applicant did not include the price of the drug in its analysis, nor did the applicant remove any charges associated with any predecessor radiopharmaceutical therapy use of MIBG agents. Based on the FY 2018 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $58,352. The applicant contended that AZEDRA® meets the cost criterion because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount before including the average per patient cost for the product.

We are concerned with the limited number of cases the applicant analyzed, and the applicant's inability to determine the exact number of cases representing patients that potentially may be eligible for treatment involving AZEDRA® for each MS–DRG. We also are concerned that the MS–DRGs identified by the applicant's search of the FY 2015 MedPAR data do not match the MS–DRGs that the applicant noted that potential cases that may be eligible for treatment involving the administration of AZEDRA® would typically map (MS–DRGs 643, 644, and 645, and MS–DRG 849). However, we acknowledge the difficulty in obtaining cost data for such a rare condition. We also note that, for the six identified MS–DRGs, the applicant's inflated average case-weighted standardized charge per case of $103,833 exceeded all individual Table 10 average case-weighted threshold amounts ($97,188 for MS–DRG 271 being the greatest). We are inviting public comments on whether the AZEDRA® technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant maintained that the use of AZEDRA® has been shown to reduce the use of antihypertensive medications, reduce tumor size, improve blood pressure control, reduce secretion of tumor biomarkers, and demonstrate strong evidence of overall survival rates. In addition, the applicant asserted that AZEDRA® provides a treatment option for those outlined in its anticipated indication patient population. The applicant asserted that AZEDRA® meets the substantial clinical improvement criterion based on the results from two clinical studies: (1) MIP–IB12 (IB12): A Phase I Study of Iobenguane (MIBG) I–131 in Patients With Malignant Pheochromocytoma/Paraganglioma; [197] and (2) MIP–IB12B (IB12B): A Study Evaluating Ultratrace® Iobenguane I–131 in Patients With Malignant Relapsed/Refractory Pheochromocytoma/Paraganglioma. The applicant explained that the IB12B study is similar to the IB12 study in that both studies evaluated two open-label, single-arm studies. The applicant reported that both studies included patients who had been diagnosed with malignant and/or recurrent and/or unresectable pheochromocytoma and Paraganglioma tumors, and both studies assessed objective tumor response, biochemical tumor response, overall survival rates, occurrence of hypertensive crisis, and the long-term benefit of AZEDRA® treatment relative to the need for antihypertensives. According to the applicant, the study designs, however, differed in dose regimens (1 dose administered to patients in the IB12 study, and 2 doses administered to patients in the IB12B study) and primary study endpoints. Differences in the designs of the studies prevented direct comparison of study endpoints and pooling of the data. However, the applicant stated that results from safety data from the IB12 study and the IB12B study were pooled and used to support substantial clinical improvement assertions. We note that the results from neither the IB12 study nor the IB12B study compared the effects of AZEDRA® to any of the other treatment options to decrease tumor burden (for example, cytotoxic chemotherapy, radiation therapy, and surgical debulking).

Regarding the data results from the IB12 study, the applicant asserted that, based on the reported safety and tolerability, and primary endpoint of radiological response at 12 months, high-specific-activity I–131 MIBG may be an effective alternative therapeutic option for patients who have been diagnosed with iobenguane-avid, metastatic and/or recurrent pheochromocytoma and paraganglioma tumors for whom there are no approved therapies and for those patients who have failed available treatment options. In addition, the applicant used the exploratory finding of decreased or discontinuation of antihypertensive medications relative to baseline medications as evidence that AZEDRA® has clinical benefit and positive impact on the long-term effects of hypertension induced norepinephrine producing malignant pheochromocytoma and paraganlioma tumors. We understand that the applicant used antihypertensive medications as a proxy to assess the long-term effects of hypertension such as renal, myocardial, and cerebral end organ damage. The applicant reported that it studied 15 of the original IB12 study's 21-patient cohort, and found 33 percent (n=5) had decreased or discontinuation of antihypertensive medications during the 12 months of follow-up. The applicant did not provide additional data on the incidence of renal insufficiency/failure, myocardial ischemic/infarction events, or transient ischemic attacks or strokes. It was unclear to us if these five patients also had decreased urine metanephrines, changed their diet, lost significant weight, or if other underlying comorbidities that influence hypertension were resolved, making it difficult to understand the significance of this exploratory finding.

Regarding the applicant's assertion that the use of AZEDRA® is safer and more effective than alternative therapies, we note that the IB12 study was a dose-escalating study and did not compare current therapies with AZEDRA®. We also note the following: (1) The average age of the 21 enrolled patients in the IB12 study was 50.4 years old (a range of 30 to 72 years old); (2) the gender distribution was 61.9 percent (n=13) male and 38.1 percent (n=8) female; and (3) 76.2 percent (n=16) were white, 14.3 percent (n=3) were black or African American, and 9.5 percent (n=2) were Asian. We agree with the study's conductor [198] that the size of the study is a limitation, and with a younger, predominately white, male patient population, generalization of study results to a more diverse population may be difficult. The applicant reported that one other aspect of the patient population indicated that all 21 patients received prior anti-cancer therapy for treatment of malignant

[197] Noto, Richard B., et al., ''Phase 1 Study of High-Specific-Activity I–131 MIBG for Metastatic and/or Recurrent Pheochromocytoma or Paraganglioma (IB12 Phase 1 Study),'' *J Clin Endocrinol Metab,* vol. 103(1), pp. 213–220.

[198] Noto, Richard B., et. al., ''Phase 1 Study of High-Specific-Activity I–131 MIBG for Metastatic and/or Recurrent Pheochromocytoma or Paraganglioma (IB12 Phase 1 Study),'' *J Clin Endocrinol Metab,* vol. 103(1), pp. 213–220.

pheochromocytoma and paraganglioma tumors, which included the following: 57.1 Percent (n=12) received radiation therapy including external beam radiation and conventional MIBG; 28.6 percent (n=6) received cytotoxic chemotherapy (for example, CVD and other chemotherapeutic agents); and 14.3 percent (n=3) received Octreotide.[199] Although this population illustrates a population that has failed some of the currently available therapy options, which may potentially support a finding of substantial clinical improvement for those with no other treatment options, we are unclear which patients benefited from treatment involving AZEDRA®, especially in view of the finding of a Fitzgerald et al. study cited earlier [200] that tissues previously irradiated by ERBT were found to be unresponsive to subsequent treatment with ^{131}I–MIBG radionuclide. It was not clear in the application how previously ERBT-treated patients who failed ERBT fared with the RECIST scores, biotumor marker results, and reduction in antihypertensive medications. We also lacked information to draw the same correlation between previously CVD-treated patients and their RECIST scores, biotumor marker results, and reduction in antihypertensive medications.

The applicant asserted that the use of AZEDRA® reduces tumor size and reduces the secretion of tumor biomarkers, thereby providing important clinical benefits to patients. The IB12 study assessed the overall best tumor response based on Response Evaluation Criteria in Solid Tumors (RECIST).[201] Tumor biomarker response was assessed as complete or partial response for serum chromogranin A and total metanephrines in 80 percent and 64 percent of patients, respectively, and the applicant noted that both the overall best tumor response based on RECIST and tumor biomarker response favorable results are at doses higher than 500 mCi. We noticed that tumor burden improvement, as measured by RECIST criteria, showed that none of the 21 patients achieved a complete response. In addition, although 4 patients showed partial response, these 4 patients also experienced dose-limiting toxicity with hematological events, and that all 4 patients received administered doses greater than 18.5 GBq (500 mCi). We also note that, regardless of total administered activity (for example, greater than or less than 18.5 GBq (500 mCi)), 61.9 percent (n=13) of the 21 patients enrolled in the study had stable disease and 14.3 percent (n=2) of the 14 patients who received greater than administered doses of 18.5 GBq (500 mCi) had progressive disease. Finally, we also noticed that, for most tumor markers, there were no dose relationship trends. While we recognize that there is no FDA-approved therapy for patients who have been diagnosed with ^{131}I–MIBG avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, we have questions as to whether the overall tumor best response and overall best tumor marker data results from the IB12 study support a finding that the AZEDRA® technology represents a substantial clinical improvement.

Finally, regarding the applicant's assertion that, based on the IB12 study data, AZEDRA® provides a safe alternative therapy for those patients who have failed other currently available treatment therapies, we note that none of the patients experienced hypertensive crisis, and that 76 percent (n=16) of the 21 patients enrolled in the study experienced Grade III or IV adverse events. Although the applicant indicated the adverse events were related to the study drug, the applicant also noted that there was no statistically significant difference between the greater than or less than 18.5 GBq administered doses; both groups had adverse events rates greater than 75 percent. Specifically, 5 of 7 patients (76 percent) who received less than or equal to 18.5 GBq administered doses, and 11 of 14 patients (79 percent) who received greater than 18.5 GBq administered doses experienced Grade III or IV adverse advents. The most common (greater than or equal to 10 percent) Grade III and IV adverse events were neutropenia, leukopenia, thrombocytopenia, nausea, and vomiting. We also note that: (1) There were 5 deaths during the study that occurred from approximately 2.5 months up to 22 months after treatment and there was no detailed data regarding the 5 deaths, especially related to the total activity received during the study; (2) there was no information about which patients received prior radiation therapy with EBRT and/or conventional MIBG relative to those who experienced Grade III or IV adverse events; and (3) the total lifetime radiation dose was not provided by the applicant. We are inviting public comments on whether the safety data profile from the IB12 study supports a finding that AZEDRA® represents a substantial clinical improvement for patients who received treatment with ^{131}I–MIBG for a diagnosis of avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma tumors, given the risks for Grade III or IV adverse events.

The applicant provided study data results from the IB12B study (MIP–IB12B), an open-label, prospective 5-year follow-up, single-arm, multi-center, Phase II pivotal study to evaluate the safety and efficacy of the use of AZEDRA® for the treatment of patients who have been diagnosed with malignant and/or recurrent pheochromocytoma and paraganglioma tumors to support substantial clinical improvement. The applicant reported that IB12B's primary endpoint is the proportion of patients with a reduction (including discontinuation) of all antihypertensive medication by at least 50 percent for at least 6 months. Seventy-four patients who received at least 1 dosimetric dose of AZEDRA® were evaluated for safety and 68 patients who received at least 1 therapeutic dose of AZEDRA®, each at 500 mCi (or 8 mCi/kg for patients weighing less than or equal to 62.5 kg), were assessed for specific clinical outcomes. The applicant asserted that results from this prospective study met the primary endpoint (reduction or discontinuation of anti-hypertensive medications), as well as demonstrated strong supportive evidence from key secondary endpoints (overall tumor response, tumor biomarker response, and overall survival rates) that confers important clinical relevance to patients who have been diagnosed with malignant pheochromocytoma and paraganlioma tumors. The applicant also indicated that the use of AZEDRA® was shown to be generally well tolerated at doses administered at 8 mCi/kg. We note that the data results from the IB12B study did not have a comparator arm, making it difficult to interpret the clinical outcome data relative to other currently available therapies.

As discussed for the IB12 study, the applicant reported that antihypertension treatment was a proxy for effectiveness of AZEDRA® on norepinephrine induced hypertension producing tumors. In the IB12B study, 25 percent (17/68) of patients met the primary

[199] Ibid.

[200] Fitzgerald, P.A., Goldsby, R.E., Huberty, J.P., et al., ''Malignant pheochromocytomas and paragangliomas: a phase II study of therapy with high-dose 131I-metaiodobenzylguanidine (131I–MIBG).'' *Ann N Y Acad Sci,* 2006, vol. 1073, pp. 465.

[201] Therasse, P., Arbuck, S.G., Eisenhauer, J.W., Kaplan, R.S., Rubinsten, L., Verweij, J., Van Blabbeke, M., Van Oosterom, A.T., Christian, M.D., and Gwyther, S.G., ''New guidelines to evaluate the response to treatment in solid tumors,'' *J Natl Cancer Inst,* 2000, vol. 92(3), pp. 205–16. Available at: *http://www.eortc.be/Services/Doc/RECIST.pdf.*

endpoint of having a greater than 50 percent reduction in antihypertensive agents for at least 6 months. The applicant further indicated that an additional 16 patients showed a greater than 50 percent reduction in antihypertensive agents for less than 6 months, and pooling data results from these 33 patients, the applicant concluded that 49 percent (33/68) achieved a greater than 50 percent reduction at any time during the study 12-month follow-up period. The applicant further compared its data results from the IB12B study regarding antihypertension medication and the frequency of post-infusion hypertension with published studies on MIBG and CVD therapy. The applicant noted a retrospective analysis of CVD therapy of 52 patients who had been diagnosed with metastatic pheochromocytoma and paraganliom tumors that found only 15 percent of CVD-treated patients achieved a 50-percent reduction in antihypertensive agents. The applicant also compared its results for post-infusion hypertension with literature reporting on MIBG and found 14 and 19 percent (depending on the study) of patients receiving MIBG experience hypertension within 24 hours of infusion. Comparatively, the applicant stated that the use of AZEDRA® had no acute events of hypertension following infusion. We are inviting public comments on whether these data results regarding hypertension support a finding that the AZEDRA® technology represents a substantial clinical improvement, and if antihypertensive medication reduction is an adequate proxy for improvement in renal, cerebral, and myocardial end organ damage.

Regarding reduction in tumor burden (as defined by RECIST scores), the applicant indicated that at the conclusion of the IB12B 12-month follow-up period, 23.4 percent (n=15) of the 68 patients showed a partial response (PR), 68.8 percent (n=44) of the 68 patients achieved stable disease (SD), and 4.7 percent (n=3) of the 68 patients showed progressive disease. None of the patients showed completed response (CR). The applicant maintained that achieving SD is important for patients who have been treated for malignant pheochromocytoma and paraganglioma tumors because this is a progressive disease without a cure at this time. The applicant also indicated that literature shows that SD is maintained in approximately 47 percent of treatment naïve patients who have been diagnosed with metastatic pheochromocytoma and paraganglioma tumors at 1 year due to the indolent nature of the disease.[202] In the IB12B study, the data results equated to 23 percent of patients achieving partial response and 69 percent of patients achieving stable disease. According to the applicant, this compares favorably to treatment with both conventional radiolabeled MIBG and CVD chemotherapy.

The applicant stated that the data results demonstrated effective tumor response rates. The applicant reported that the IB12 and IB12B study data showed overall tumor response rates of 80 percent and 92 percent, respectively. In addition, the applicant contended that the study data across both trials show that patients demonstrated improved blood pressure control, reductions in tumor biomarker secretion, and strong evidence in overall survival rates. The overall median time to death from the first dose was 36.7 months in all treated patients. Patients who received 2 therapeutic doses had an overall median survival rate of 48.7 months, compared to 17.5 months for patients who only received a single dose.

The applicant indicated that comparison of IB12B study data regarding overall survival rate with historical data is difficult due to the differences in the retrospective and heterogeneous nature of the published clinical studies and patient characteristics, especially when overall survival is calculated from the time of initial diagnosis. We agree with the applicant regarding the difficulties in comparing the results of the published clinical studies, and also believe that the differences in these studies may make it more difficult to evaluate whether the use of the AZEDRA® technology improves overall survival rates relative to other therapies.

We acknowledge the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients who have been diagnosed with pheochromocytoma and paraganglioma tumors. However, we are concerned that because the data for both of these studies is mainly based upon retrospective studies and small, heterogeneous patient cohorts, it is difficult to draw strong conclusions regarding efficacy. Only very limited nonpublished data from two, single-arm, noncomparative studies are available to evaluate the safety and effectiveness of Ultratrace® I–131 MIBG, leading to a comparison of outcomes with historical controls. We are inviting public comments on whether the use of the AZEDRA® technology meets the substantial clinical improvement criterion, including with respect to the specific concerns we have raised.

Below we summarize and respond to two written public comments we received during the open comment period in response to the published notice in the **Federal Register** announcing the New Technology Town Hall Meeting regarding the substantial clinical improvement criterion aspect of AZEDRA®'s application for new technology add-on payments for FY 2019 below.

Comment: One commenter supported the approval of the application of AZEDRA® for new technology add-on payments for FY 2019 and its substantial clinical improvement in the treatment options available for Medicare beneficiaries. The commenter believed that AZEDRA® demonstrates a substantial clinical improvement over other available therapies (as described previously) and meets a current unmet need for the treatment of patients who have been diagnosed with pheochromocytoma and paraganglioma. The commenter stated that AZEDRA®'s structure is unlike the structure of any existing treatment option, given the use of the Ultratrace® technology which has demonstrated resulting occurrences of reduced serious cardiovascular side effects and increased efficacy due to its unique ''carrier-free'' structure.

Another commenter also supported the approval of new technology add-on payments for AZEDRA® and its substantial clinical improvement in the treatment options available for Medicare beneficiaries. This commenter stated that AZEDRA® is much simpler to administer than low-specific activity I–131 MIBG, offers quicker and simpler infusions, and provides a rational, personalized, and effective therapy with promising and highly significant clinical benefits for patients who have been diagnosed with advanced pheochromocytoma and paraganglioma.

Response: We appreciate the commenters' input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for AZEDRA® for FY 2019.

m. The AquaBeam System (Aquablation)

PROCEPT BioRobotics Corporation submitted an application for new technology add-on payments for the

[202] Hescot, S., Leboulleux, S., Amar, L., Vezzosi, D., Borget, I., Bournaud-Salinas, C., de la Fouchardiere, C., Libé, R., Do Cao, C., Niccoli, P., Tabarin, A., ''One-year progression-free survival of therapy-naive patients with malignant pheochromocytoma and paraganglioma,'' *The J Clin Endocrinol Metab,* 2013, vol. 98(10), pp. 4006–4012.

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). The AquaBeam System consists of three main components: A console with two high-pressure pumps, a conformal surgical planning unit with trans-rectal ultrasound imaging, and a single-use robotic hand-piece.

The applicant reported that The AquaBeam System provides the operating surgeon a multi-dimensional view, using both ultrasound image guidance and endoscopic visualization, to clearly identify the prostatic adenoma and plan the surgical resection area. Based on the planning inputs from the surgeon, the system's robot delivers Aquablation, an autonomous waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue used for the purpose of treating lower urinary tract symptoms caused by a diagnosis of BPH. The combination of surgical mapping and robotically-controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size, prostate shape or surgeon experience.

In its application, the applicant indicated that benign prostatic hyperplasia (BPH) is one of the most commonly diagnosed conditions of the male genitourinary tract [203] and is defined as the ''. . . enlargement of the prostate due to benign growth of glandular tissue . . .'' in older men.[204] BPH is estimated to affect 30 percent of males that are older than 50 years old.[205] [206] BPH may compress the urethral canal possibly obstructing the urethra, which may cause symptoms that effect the lower urinary tract, such as difficulty urinating (dysuria), hesitancy, and frequent urination.[207] [208] [209]

The initial treatment for a patient who has been diagnosed with BPH is watchful waiting and medications.[210] Symptom severity, as measured by one test, the International Prostate Symptom Score (IPSS), is the primary measure by which surgery necessity is decided.[211] Many techniques exist for the surgical treatment of patients who have been diagnosed with BPH, and these surgical treatments differ primarily by the method of resection: Electrocautery in the case of Transurethral Resection of the Prostate (TURP), laser enucleation, plasma vaporization, photoselective vaporization, radiofrequency ablation, microwave thermotherapy, and transurethral incision [212] are among the primary methods. TURP is the primary reference treatment for patients who have been diagnosed with BPH.[213] [214] [215] [216] [217]

According to the applicant, while the TURP procedure achieves alleviation of the symptoms that affect the lower urinary tract associated with a diagnosis of BPH, morbidity rates caused by adverse events are high following the procedure. The TURP procedure has a well-documented history of associated adverse effects, such as hematuria, clot retention, bladder wall injury, hyponatremia, bladder neck contracture, urinary incontinence, and retrograde ejaculation.[218] [219] [220] [221] [222] The likelihood of both adverse events and long-term morbidity related to the TURP procedure increase with the size of the prostate.[223]

The applicant asserted that the AquaBeam System provides superior safety outcomes as compared to the

[203] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

[204] Gilling, P., Anderson, P., and Tan, A., ''Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year results,'' *The Journal of Urology,* 2017, vol. 197, pp. 156–1572.

[205] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[206] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[207] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[208] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[209] Roehrborn, C., Gilling, P., Cher, D., andTemplin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

[210] Ibid.

[211] Cunningham, G. R., Kadmon, D., 2017, ''Clinical manifestations and diagnostic evaluation of benign prostatic hyperplasia,'' 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnostic-evaluation-of-benign-prostatic-hyperplasia?search=cunningham%20kadmon%202017%20benign%20prostatic&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2.*

[212] Ibid.

[213] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

[214] Cunningham, G. R., Kadmon, D., ''Clinical manifestations and diagnostic evaluation of benign prostatic hyperplasia,'' 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnostic-evaluation-of-benign-prostatic-hyperplasia?search=cunningham%20kadmon%202017%20benign%20prostatic&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2.*

[215] Mamoulakis, C., Efthimiou, I., Kazoulis, S., Christoulakis, I., and Sofras, F., ''The Modified Clavien Classification System: A standardized platform for reporting complications in transurethral resection of the prostate,'' *World Journal of Urology,* 2011, vol. 29, pp. 205–210.

[216] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[217] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[218] Roehrborn, C., Gilling, P., Cher, D., and Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

[219] Cunningham, G. R., & Kadmon, D., 2017, ''Clinical manifestations and diagnostic evaluation of benign prostatic hyperplasia,'' 2017. Available at: *https://www.uptodate.com/contents/clinical-manifestations-and-diagnostic-evaluation-of-benign-prostatic-hyperplasia?search=cunningham%20kadmon%202017%20benign%20prostatic&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2.*

[220] Mamoulakis, C., Efthimiou, I., Kazoulis, S., Christoulakis, I., Sofras, F., ''The Modified Clavien Classification System: A standardized platform for reporting complications in transurethral resection of the prostate,'' *World Journal of Urology,* 2011, vol. 29, pp. 205–210.

[221] Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalist, D., ''The Prostatic Urethral Lift for the Treatmentof Lower Urinary Tract Symptoms Associated with Prostate Enlargement Due to Benign Prostatic Hyperplasia: The LIFT study,'' *The Journal of Urology,* 2013, vol. 190, pp. 2161–2167.

[222] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

[223] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

TURP procedure, while providing non-inferior efficacy in treating the symptoms that affect the lower urinary tract associated with a diagnosis of BPH. The applicant further stated that the AquaBeam System yields consistent and predictable procedure and resection times regardless of the size and shape of the prostate and the surgeon's experience. Lastly, according to the applicant, the AquaBeam System provides increased efficacy and safety for larger prostates as compared to the TURP procedure.

With respect to the newness criterion, FDA granted the applicant'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 applicant stated that the AquaBeam System was made available on the U.S. market immediately after the FDA granted the *De Novo* request. Therefore, if approved for new technology add-on payments, the newness period is considered to begin on December 21, 2017. There are currently no existing ICD–10–PCS procedure codes to specifically identify procedures involving the Aquablation method or technique for the treatment of symptoms that affect the lower urinary tract in patients who have been diagnosed with BPH. The applicant stated that it applied for approval for a distinct ICD-10–PCS procedure code to uniquely identify procedures involving the AquaBeam System at the ICD–10 Maintenance and Coordination Committee March 2018 meeting.

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 the 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 stated that the AquaBeam System is the first technology to deliver treatment to patients who have been diagnosed with BPH for the symptoms that effect the lower urinary tract caused by BPH via Aquablation therapy. The AquaBeam System utilizes intra-operative image guidance for surgical planning and then Aquablation therapy to robotically resect tissue utilizing a high-velocity waterjet. According to the applicant, all other BPH treatment procedures only utilize cystoscopic visualization, whereas the AquaBeam System utilizes Aquablation therapy, a combination of cystoscopic visualization and intra-operative image guidance. According to the applicant, the AquaBeam System's use of Aquablation therapy qualifies it as the only technology to utilize a high-velocity room temperature waterjet for tissue resection, while most other BPH surgical procedures utilize thermal energy to resect prostatic tissue, or require the implantation of clips to pull back prostatic tissue blocking the urethra. Lastly, according to the applicant, all other surgical modalities are executed by the operating surgeon, while the AquaBeam System allows planning by the surgeon and utilization of Aquablation therapy ensures accurate and efficient tissue resection is autonomously executed by the robot.

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 potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy technique will ultimately map to the same MS–DRGs as cases for existing BPH treatment options.

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 stated that the AquaBeam System's Aquablation therapy will ultimately treat the same patient population as other available BPH treatment options. The applicant asserted that the AquaBeam System's Aquablation therapy has been shown to be more effective and safer than the TURP procedure for patients with larger prostate sizes. The applicant stated that prostates 80 ml or greater in size are not appropriate for the TURP procedure and, therefore, more intensive procedures such as surgery are required. Furthermore, the applicant claimed that the AquaBeam System's Aquablation therapy is particularly appropriate for smaller prostate sizes, ~30 ml, due to increased accuracy provided by both the computer assistance and ultrasound visualization.

We have the following concerns regarding whether the AquaBeam System meets the newness criterion. Currently, there are many treatment options that utilize varying forms of ablation, such as mono and bipolar TURP procedures, laser, microwave, and radiofrequency, to treat the symptoms associated with a diagnosis of BPH. We are concerned that, while this device utilizes water to perform any tissue removal, its mechanism of action may not be different from that of other forms of treatment for patients who have been diagnosed with BPH. Further, the use of water to perform tissue removal in the treatment of associated symptoms in patients who have been diagnosed with BPH has existed in other areas of surgical treatment prior to the introduction of this product (for example, endometrial ablation and wound debridement). In addition, the standard operative treatment, such as with the TURP procedure, for patients who have been diagnosed with BPH is to widen the urethra compressed by an enlarged prostate in an effort to alleviate the negative effects of an enlarged prostate. Like other existing methods, the AquaBeam System's Aquablation therapy also ablates tissue to enlarge compression of the urethra. Additionally, while the robotic arm and computer programing may result in different outcomes for patients, we are uncertain that the use of the robotic hand and computer programming result in a new mechanism of action. We are inviting public comments on this issue.

We also are inviting public comments on whether the AquaBeam System's Aquablation therapy 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. Given that the AquaBeam System's Aquablation therapy procedure does not currently have a unique ICD–10–PCS procedure code, the applicant searched the FY 2016 MedPAR data file for cases with the following current ICD–10–PCS codes describing other BPH minimally invasive procedures to identify potential cases representing potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy: 0V507ZZ (Destruction of prostate, via natural or artificial opening), 0V508ZZ (Destruction of prostate, via natural or artificial opening endoscopic), 0VT07ZZ (Resection of prostate, via natural or artificial opening), and 0VT08ZZ (Resection of prostate, via natural or artificial opening endoscopic). The applicant identified a total of 133 MS–DRGs using these ICD–10–PCS codes.

In order to calculate the standardized charges per case, the applicant conducted two analyses, based on 100 percent and 75 percent of identified claims in the FY 2016 MedPAR data file. The applicant based its analysis on 100 percent of claims mapping to 133 MS–DRGs, and 75 percent of claims mapping to 6 MS–DRGs. The cases identified in the 75 percent analysis mapped to MS–DRGs 665 (Prostatectomy with MCC), 666

(Prostatectomy with CC), 667 (Prostatectomy without CC/MCC), 713 (Transurethral Prostatectomy with CC/MCC), 714 (Transurethral Prostatectomy without CC/MCC), and 988 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC). In situations in which there were fewer than 11 cases for individual MS–DRGs in the MedPAR data file, a value of 11 was imputed to ensure confidentiality for patients. When evaluating 100 percent of the cases identified, the applicant included low–volume MS–DRGs that had equal to or less than 11 total cases to represent potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy in order to calculate the average case–weighted unstandardized and standardized charge amounts. The 75 percent analysis removed those MS–DRGs with 11 cases or less representing potential patients who may be eligible for treatment involving the AquaBeam System's Aquablation therapy, resulting in only 6 of the 133 MS–DRGs remaining for analysis. A total of 8,449 cases were included in the 100 percent analysis and 6,285 cases were included in the 75 percent analysis.

Using the 100 percent and 75 percent samples, the applicant determined that the average case-weighted unstandardized charge per case was $69,662 and $47,475, respectively. The applicant removed 100 percent of total charges associated with the service category ''Medical/Surgical Supply Charge Amount'' (which includes revenue centers 027x and 062x) because the applicant believed that it was the most conservative choice, as this amount varies by MS–DRG. The applicant stated that the financial impact of utilizing the AquaBeam System's Aquablation therapy on hospital resources other than on ''Medical Supplies'' is unknown at this time. Therefore, a value of $0 was used for charges related to the prior technology.

The applicant standardized the charges, and inflated the charges using an inflation factor of 1.09357, from the FY 2018 IPPS/LTCH PPS final rule (82 FR 38524). The applicant then added the charges for the new technology. The applicant computed a final inflated average case-weighted standardized charge per case of $69,588 for the 100 percent sample, and $51,022 for the 75 percent sample. The average case-weighted threshold amount was $59,242 for the 100 percent sample, and $48,893 for the 75 percent sample. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount for both analyses, the applicant maintained that the technology meets the cost criterion.

We are inviting public comment regarding whether the technology meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Aquablation therapy provided by the AquaBeam System represents a substantial clinical improvement over existing treatment options for symptoms associated with the lower urinary tract for patients who have been diagnosed with BPH. Specifically, the applicant stated that the AquaBeam System's Aquablation therapy provides superior safety outcomes compared to the TURP procedure, while providing noninferior efficacy in treating the symptoms that effect the lower urinary tract associated with a diagnosis of BPH; the AquaBeam System's delivery of Aquablation therapy yields consistent and predictable procedure and resection times regardless of the size and shape of the prostate or the surgeon's experience; and the AquaBeam System's Aquablation therapy demonstrated superior efficacy and safety for larger prostates (that is, prostates sized 50 to 80 mL) as compared to the TURP procedure.

The applicant provided the results of one Phase I and one Phase II trial published articles, the WATER Study Clinical Study Report, and a meta-analysis of current treatments with its application as evidence for the substantial clinical improvement criterion.

According to the applicant, the first study [224] enrolled 15 nonrandomized patients with a prostate volume between 25 to 80 ml in a Phase I trial testing the safety and feasibility of the AquaBeam System's Aquablation therapy; all patients received the AquaBeam System's Aquablation therapy. This study, a prospective, nonrandomized study, enrolled men who were 50 to 80 years old who were affected by moderate to severe lower urinary tract symptoms, who did not respond to standard medical therapy.[225] Follow-up assessments were conducted at 1, 3, and 6 months and included information on adverse events, serum PSA level, uroflowmetry, PVR, quality of life, and the International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF) scores. The primary outcome was the assessment of safety as measured by adverse event reporting; secondary endpoints focused on alleviation of BPH symptoms.[226]

The applicant indicated that 8 of the 15 patients who were enrolled in the trial had at least 1 procedure-related adverse event (for example, catheterization, hematuria, dysuria, pelvic pain, bladder spasms), which the authors reported to be consistent with outcomes from minimally-invasive transurethral procedures.[227] There were no occurrences of incontinence, retrograde ejaculation, or erectile dysfunction at 30 days.[228] Statistically significant improvement on all outcomes occurred over the 6-month period. Average IPSS scores showed a negative slope with scores of 23.1, 11.8, 9.1, and 8.6 for baseline, 1 month, 3 months, and 6 months ($p<0.01$ in all cases). Average quality of life scores, which range from 1 to 5, where 1 is better and 5 is worse, decreased from 5.0 at baseline to 2.6 at 1 month, 2.2 at 3 months, and 2.5 at 6 months. Average maximum urinary flow rate increased steadily across time points from 8.6 ml/s at baseline to 18.6 ml/s at 6 months. Lastly, average post-void residual urine volume decreased from 91 ml at baseline to 38 ml at 1 month, 60 ml at 3 months, and 30 ml at 6 months.[229]

The second study [230] presents results from a Phase II trial involving 21 men with a prostate volume between 30 to 102 ml who received treatment involving the AquaBeam System's Aquablation therapy with follow-up at 1 year. This prospective study enrolled men between the ages of 50 and 80 years old who were effected by moderate to severe symptomatic BPH.[231] The primary end point was the rate of adverse events; the secondary end points measured alleviation of symptoms associated with a diagnosis of BPH. Data was collected at baseline and at 1 month, 3 months, 6 months, and 12 months; 1 patient withdrew at 3 months. The authors asserted that the occurrence of post-operative adverse events (urinary retention, dysuria, hematuria, urinary tract infection, bladder spasm, meatal stenosis) were consistent with other minimally-invasive transurethral

[224] Gilling P., Reuther, R., Kahokehr, A., Fraundorfer, M., ''Aquablation—Image-guided Robot-assisted Waterjet Ablation of the Prostate: Initial clinical experience,'' *British Journal of Urology International,* 2016, vol. 117, pp. 923–929.

[225] Ibid.

[226] Ibid.

[227] Gilling, P., Anderson, P., and Tan, A., ''Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year results,'' *The Journal of Urology,* 2017, vol. 197, pp. 156–1572.

[228] Ibid.

[229] Ibid.

[230] Ibid.

[231] Ibid.

procedures; [232] 6 patients had at least 1 adverse event, including temporary urinary symptoms and medically-treated urinary tract infections.[233] The mean IPSS scores decreased from the baseline of 22.8 with 11.5 at 1 month, 7 at 3 months, 7.1 at 6 months, and 6.8 at 12 months and were statistically significantly different. Similarly, quality of life decreased from a mean score of 5 at baseline to 1.7 at 12 months, all time points were statistically significantly different from the baseline.

The third document provided by the applicant is the Clinical Study Report: WATER Study,[234] a prospective multi-center, randomized, blinded study. The WATER Study compared the AquaBeam System's Aquablation therapy to the TURP procedure for the treatment of lower urinary tract symptoms associated with a diagnosis of BPH. One hundred eighty one (181) patients with prostate volumes between 30 and 80 ml were randomized, 65 patients to the TURP procedure group and the other 116 to the AquaBeam System's Aquablation therapy group, with 176 (97 percent of patients) continuing at 3 and 6 month follow-up, where 2 missing patients received treatment involving the AquaBeam System's Aquablation therapy and 3 received treatment involving the TURP procedure; randomization efficacy was assessed and confirmed with findings of no statistical differences between cases and controls among all characteristics measures, specifically prostate volume. Two primary endpoints were identified: (1) The safety endpoint was the proportion of patients with adverse events rates as ''probably or definitely related to the study procedure'' also classified as the Clavien-Dindo (CD) Grade 2 or higher or any Grade 1 resulting in persistent disability; and (2) the primary efficacy endpoint was a change in the IPSS score from baseline to 6 months. Three secondary endpoints were based on perioperative data and were: Length of hospital stay, length of operative time, and length of resection time. The occurrences of three secondary endpoints during the 6-month follow-up were: (1) Reoperation or reintervention within 6 months; (2) evaluation of proportion of sexually active patients; and (3) evaluation of proportion of patients with major adverse urologic events.

At 3 months, 25 percent of the patients in the AquaBeam System's Aquablation therapy group and 40 percent of the patients in the TURP group had an adverse event. The difference of −15 percent has a 95 percent confidence interval of −29.2 and −1.0 percent. At 6 months, 25.9 percent of the patients in the AquaBeam System's Aquablation therapy group and 43.1 percent of the patients in the TURP group had an adverse event. The difference of −17 percent has a 95 percent confidence interval of −31.5 to −3.0 percent. An analysis of safety events classified with the CD system as possibly, probably or definitely related to the procedure resulted in a CD Grade 1 persistent event difference between −17.7 percent (favoring the AquaBeam System's Aquablation therapy) with 95 percent confidence interval of −30.1 to −7.2 percent and a CD Grade 2 or higher event difference of −3.3 percent with 95 percent confidence interval of −16.5 to 8.7 percent.

The applicant indicated that the primary efficacy endpoint was assessed by a change in IPSS score over time. While change in score and change in percentages are generally higher for the AquaBeam System's Aquablation therapy, no statistically significant differences occurred between the AquaBeam System's Aquablation therapy and the TURP procedure over time. For example, the AquaBeam System's Aquablation therapy group experienced changes in IPSS mean score by visit of 0, −3.8, −12.5, −16.0, and −16.9 at baseline, 1 week, 1 month, 3 months, and 6 months, respectively, while the TURP group had mean scores of 0, −3.6, −11.1, −14.6, and −15.1 at baseline, 1 week, 1 month, 3 months, and 6 months, respectively.

Lastly, the applicant indicated that secondary endpoints were assessed. A mean length of stay for both the AquaBeam System's Aquablation therapy and the TURP procedure groups of 1.4 was achieved. While the mean operative times were similar, the hand piece in and out time was statistically significantly shorter for the AquaBeam System's Aquablation therapy group at 23.3 minutes as compared to 34.2 in the TURP procedure group. The mean resection time was 23 minutes shorter for the AquaBeam System's Aquablation therapy group at 3.9 minutes. No statistically significant difference was seen between the AquaBeam System's Aquablation therapy and the TURP procedure groups on the outcomes of re-intervention and worsening sexual function; 32.9 percent of the AquaBeam System's Aquablation therapy group had worsening sexual function as compared to 52.8 percent of the TURP procedure group. While statistically significant differences occurred across groups for change in ejaculatory function, the difference no longer remained at 6 months. While a greater proportion of the TURP procedure group patients experienced a negative change in erectile function as compared to the AquaBeam System's Aquablation therapy group patients (10 percent versus 6.2 percent at 6 months), no statistically significant differences occurred. No statistically significant differences between groups occurred for major adverse urologic events.

The applicant provided a meta-analysis of landmark studies regarding typical treatments for patients who have been diagnosed with BPH in order to provide supporting evidence for the assertion of superior outcomes achieved with the use of the AquaBeam System's Aquablation therapy. The applicant cited four ''landmark clinical trials,'' which report on the AquaBeam System's Aquablation therapy,[235] the TURP procedure, Green light laser versus the TURP procedure,[236] and Urolift.[237] Comparisons are made between performance outcomes on three separate treatments for patients who have been diagnosed with BPH: The AquaBeam System's Aquablation therapy, the TURP procedure, and Urolift. The applicant stated that all three clinical trials included men with average IPSS baseline scores of 21 to 23 points. The applicant stated that, while total procedure times are similar across all three treatment options, the AquaBeam System's Aquablation therapy has dramatically less time and variability associated with the tissue treatment. The applicant further stated that the differences between treatment options were not assessed for statistical significance. The applicant indicated

[232] Gilling, P., Anderson, P., and Tan, A., ''Aquablation of the Prostate for Symptomatic Benign Prostatic Hyperplasia: 1-Year results,'' *The Journal of Urology,* 2017, vol. 197, pp. 156–1572.

[233] Ibid.

[234] Roehrborn, C., Gilling, P., Cher, D., Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

[235] Roehrborn, C., Gilling, P., Cher, D., Templin, B., ''The WATER Study (Waterjet Ablation Therapy for Ednoscopic Resection of prostate tissue),'' Redwood City: PROCEPT BioRobotics Corporation, 2017.

[236] Bachmann, A., Tubaro, A., Barber, N., d'Ancona, F., Muir, G., Witzsch, U., Thomas, J., ''180–W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-month safety and efficacy results of a european multicentre randomised trial—the GOLIATH study,'' *European Association of Urology,* 2014, vol. 65, pp. 931–942.

[237] Sonksen, J., Barber, N., Speakman, M., Berges, R., Wetterauer, U., Greene, D., Gratzke, C., ''Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month results from the BPH6 study,'' *European Association of Urology,* 2015, vol. 68, pp. 643–652.

that the AquaBeam System's Aquablation therapy, with an approximate score of 17, had the largest improvement in IPSS scores at 6 months as compared to 16 for the TURP procedure and 11 for Urolift. Compared to 46 percent in the TURP group, the applicant found that the AquaBeam System's Aquablation therapy and Urolift had much lower percentages, 4 percent and 0 percent, respectively, of an ejaculation-related consequence in patients. Lastly, the applicant stated that safety events, as measured by the percentage of CD Grade 2 or higher events, were lower in the AquaBeam System's Aquablation therapy (19 percent) and Urolift (14 percent) than in TURP (29 percent).

We have several concerns related to the substantial clinical improvement criterion. The applicant performed a meta-analysis comparing results from three separate studies, which tested the effects of three separate treatment options. According to the applicant, the results provided consistently show the AquaBeam System's Aquablation therapy and Urolift as being superior to the standard treatment of the TURP procedure. We have concerns with the interpretation of these results that the applicant provided. The comparison of multiple clinical studies is a difficult issue. It is not clear if the applicant took into account the varying study designs, sample techniques, and other study specific issues, such as physician skill and patient health status. For instance, the applicant stated that a comparison of Urolift and the AquaBeam System's Aquablation therapy may not be appropriate due to the differing indications of the procedures; the applicant indicated that Urolift is primarily used for the treatment of patients who have been diagnosed with BPH who have smaller prostate volumes, whereas the AquaBeam System's Aquablation therapy procedure may be used in all prostate sizes. Similarly, the applicant stated that the TURP procedure is generally not utilized in patients with prostates larger than 80ml, whereas such patients may be eligible for treatment involving the AquaBeam System's Aquablation therapy.

We note that the applicant submitted a meta-analysis in an effort to compare currently available therapies to the AquaBeam System's Aquablation therapy. The possibility of the heterogeneity of samples and methods across studies leads to the possible introduction of bias, which results in the difficulty or inability to distinguish between bias and actual outcomes. We are inviting public comments on the applicability of this meta-analysis.

Additionally, the differences between the AquaBeam System's Aquablation therapy and standard treatment options may not be as impactful and confined to safety aspects. It appears that the data on efficacy supported the equivalence of the AquaBeam System's Aquablation therapy and the TURP procedure based upon noninferiority analysis. We agree that the safety data were reported as showing superiority of the AquaBeam System's Aquablation therapy over the TURP procedure, although the data were difficult to track because adverse consequences were combined into categories; the AquaBeam System's Aquablation therapy was reportedly better in terms of ejaculatory function. It was noted in the application that, while the AquaBeam System's Aquablation therapy was statistically superior to the TURP procedure in the CD Grade 1 + adverse events, it was not statistically different in the CD Grade 2 or greater category. The applicant stated that regardless of the method, the urethra is typically used as the means for performing the BPH treatment procedure, which necessarily increases the likelihood of CD Grade 2 adverse events in all transurethral procedures.

In addition, the applicant noted that the treatment option may depend on the size of the prostate. The applicant stated that the AquaBeam System's Aquablation therapy is appropriate for small and large prostate sizes as a BPH treatment procedure. The AquaBeam System's Aquablation therapy has been shown to have limited positive outcomes as compared to the TURP procedure for prostates sized greater than 50 grams to 80 grams in each of the studies provided by the applicant. However, the applicant noted that the TURP procedure would not be used for prostates larger than 80 grams in size. Therefore, we believe that another proper comparator for the AquaBeam System's Aquablation therapy may be laser or radical/open surgical procedures given their respective indication for small and large prostate sizes.

Lastly, the applicant compared AquaBeam System's Aquablation therapy and the standard of care TURP procedure to support a finding of improved safety. There are other treatment modalities available that may have a similar safety profile as the AquaBeam System's Aquablation therapy and we are interested in information that compares the AquaBeam System's Aquablation therapy to other treatment modalities.

We are inviting public comments on whether the AquaBeam System's Aquablation therapy meets the substantial clinical improvement criterion.

We did not receive any public comments in response to the published notice in the **Federal Register** regarding the AquaBeam System's Aquablation therapy or at the New Technology Town Hall Meeting.

n. AndexXa™ (Andexanet alfa)

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2019 for the use of AndexXa™ (Andexanet alfa). (We note that the applicant previously submitted applications for new technology add-on payments for FY 2017 and FY 2018 for Andexanet alfa, which were withdrawn.)

AndexXa™ is an antidote used to treat patients who are receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Patients at high risk for thrombosis, including those who have been diagnosed with atrial fibrillation (AF) and venous thrombosis (VTE), typically receive treatment using long-term oral anticoagulation agents. Factor Xa inhibitors are included in a new class of anticoagulants. Factor Xa inhibitors are oral anticoagulants used to prevent stroke and systemic embolism in patients who have been diagnosed with AF. These oral anticoagulants are also used to treat patients who have been diagnosed with deep-vein thrombosis (DVT) and its complications, pulmonary embolism (PE), and patients who have undergone knee, hip, or abdominal surgery. Rivarobaxan (Xarelto®), apixaban (Eliqis®), betrixaban (Bevyxxa®), and edoxaban (Savaysa®) also are included in the new class of Factor Xa inhibitors, and are often referred to as ''novel oral anticoagulants'' (NOACs) or ''non-vitamin K antagonist oral anticoagulants.'' Although these anticoagulants have been commercially available since 2011, there is no FDA-approved therapy used for the urgent reversal of any Factor Xa inhibitor as a result of serious bleeding episodes.

AndexXa™ has not received FDA approval as of the time of the development of this proposed rule. The applicant indicated that it anticipates receipt of FDA approval for the use of the technology during the first quarter of 2018. The applicant received approval for two unique ICD–10–PCS procedure codes that became effective October 1,

2016 (FY 2017). The approved ICD–10–PCS procedure codes are: XW03372 (Introduction of Andexanet alfa, Factor Xa inhibitor reversal agent into peripheral vein, percutaneous approach, new technology group 2); and XW04372 (Introduction of Andexanet alfa, Factor Xa inhibitor reversal agent into central vein, percutaneous approach, new technology group 2).

With regard to the ''newness'' criterion, 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 purposes of new technology add-on payments. The applicant asserted that, if approved, AndexXa™ would be the first and the only antidote available used to treat patients who are receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Therefore, the applicant asserted that the technology is not substantially similar to any other currently approved and available treatment options for Medicare beneficiaries. Below we discuss the applicant's assertion in the context of the three substantial similarity criteria.

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, AndexXa™, if approved, would be the first anticoagulant reversal agent that binds to direct Factor Xa inhibitors with high affinity, thereby sequestering the inhibitors and consequently rapidly reducing free plasma concentration of Factor Xa inhibitors, and neutralizing the inhibitors' anticoagulant effect, which allows for the restoration of normal hemostasis. AndexXa™ also binds to and sequesters antithrombin III molecules that are complexed with indirect inhibitor molecules, which disrupts the capacity of the antithrombin complex to bind to native Factor Xa inhibitors. According to the applicant, AndexXa™ represents a significant therapeutic advance because it provides rapid reversal of anticoagulation therapy in the event of a serious bleeding episode. Other anticoagulant reversal agents, such as Kcentra™ and Idarucizumab, do not reverse the effects of Factor Xa inhibitors.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, AndexXa™ would be the first FDA-approved anticoagulant reversal agent for Factor Xa inhibitors. Therefore, the MS–DRGs do not contain cases that represent patients who have been treated with any anticoagulant reversal agents for Factor Xa inhibitors.

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 stated that AndexXa™, if approved, would be the only anticoagulant reversal agent available for treating patients who are receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery. Therefore, the applicant believed that AndexXa™ would be the first type of treatment option available to this patient population. As a result, we believe that it appears that AndexXa™ is not substantially similar to any existing technologies. We are inviting public comments on whether AndexXa™ meets the substantial similarity criteria, and whether AndexXa™ meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2015 MedPAR claims data file for potential cases representing patients who may be eligible for treatment using AndexXa™. The applicant used three sets of ICD–9–CM codes to identify these cases: (1) Codes identifying potential cases representing patients who were treated with an anticoagulant and, therefore, who are at risk of bleeding; (2) codes identifying potential cases representing patients with a history of conditions that were treated with Factor Xa inhibitors; and (3) codes identifying potential cases representing patients who experienced bleeding episodes as the reason for the current admission. The applicant included with its application the following table displaying a complete list of ICD–9–CM codes that met its selection criteria.

ICD–9–CM codes applicable	Applicable ICD–9–CM code description
V12.50	Personal history of unspecified circulatory disease.
V12.51	Personal history of venous thrombosis and embolism.
V12.52	Personal history of thrombophlebitis.
V12.54	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits.
V12.55	Personal history of pulmonary embolism.
V12.59	Personal history of other diseases of circulatory system.
V43.64	Hip joint replacement.
V43.65	Knee joint replacement.
V58.43	Aftercare following surgery for injury and trauma.
V58.49	Other specified aftercare following surgery.
V58.73	Aftercare following surgery of the circulatory system, NEC.
V58.75	Aftercare following surgery of the teeth, oral cavity and digestive system, NEC.
V58.61	Long-term (current) use of anticoagulants.
E934.2	Anticoagulants causing adverse effects in therapeutic use.
99.00	Perioperative autologous transfusion of whole blood or blood components.
99.01	Exchange transfusion.
99.02	Transfusion of previously collected autologous blood.
99.03	Other transfusion of whole blood.
99.04	Transfusion of packed cells.
99.05	Transfusion of platelets.
99.06	Transfusion of coagulation factors.
99.07	Transfusion of other serum.

The applicant identified a total of 51,605 potential cases that mapped to 683 MS–DRGs, resulting in an average case-weighted charge per case of $72,291. The applicant also provided an analysis that was limited to cases

representing 80 percent of all potential cases identified (41,255 cases) that mapped to the top 151 MS–DRGs. Under this analysis, the average case-weighted charge per case was $69,020. The applicant provided a third analysis that was limited to cases representing 25 percent of all potential cases identified (12,873 cases) that mapped to the top 9 MS–DRGs. This third analysis resulted in an average case-weighted charge per case of $46,974.

Under each of these analyses, the applicant also provided sensitivity analyses based on variables representing two areas of uncertainty: (1) Whether to remove 40 percent or 60 percent of blood and blood administration charges; and (2) whether to remove pharmacy charges based on the ceiling price of factor eight inhibitor bypass activity (FEIBA), a branded anti-inhibitor coagulant complex, or on the pharmacy indicator 5 (PI5) in the MedPAR data file, which correlates to potential cases utilizing generic coagulation factors. Overall, the applicant conducted twelve sensitivity analyses, and provided the following rationales:

- The applicant chose to remove 40 percent and 60 percent of blood and blood administration charges because potential patients who may be eligible for treatment using AndexXa™ for Factor Xa reversal may still require blood and blood products to treat other conditions. Therefore, the applicant believed that it would be inappropriate to remove all of the charges associated with blood and blood administration because all of the charges cannot be attributed to Factor Xa reversal. The applicant maintained that the amounts of blood and blood products required for treatment vary according to the severity of the bleeding. Therefore, the applicant stated that the use of AndexXa™ may replace 60 percent of blood and blood product administration charges for potential cases with less severity of bleeding, but only 40 percent of charges for potential cases with more severe bleeding.
- The applicant maintained that FEIBA is the highest priced clotting factor used for Factor Xa inhibitor reversal, and it is unlikely that pharmacy charges for Factor Xa reversal would exceed the FEIBA ceiling price of $2,642. Therefore, the applicant capped the charges to be removed at $2,642 to exclude charges unrelated to the reversal of Factor Xa anticoagulation. The applicant also considered an alternative scenario in which charges associated with pharmacy indicator 5 (PI5) were removed from the costs of potential cases that included this indicator in the MedPAR data. On average, charges removed from the costs of potential cases utilizing generic coagulation factors were much lower than the total pharmacy charges.

The applicant noted that, in all 12 scenarios, the average case-weighted standardized charge per case for potential cases representing patients who may be eligible for treatment using AndexXa™ would exceed the average case-weighted threshold amounts in Table 10 of the FY 2018 IPPS/LTCH PPS final rule by more than $855.

The applicant's order of operations used for each analysis is as follows: (1) Removing 60 percent or 40 percent of blood and blood product administration charges and up to 100 percent of pharmacy charges for PI5 or FEIBA from the average case-weighted unstandardized charge per case; and (2) standardizing the charges per cases using the Impact File published with the FY 2015 IPPS/LTCH PPS final rule. After removing the charges for the prior technology and standardizing charges, the applicant applied an inflation factor of 1.154181, which is a combination of 9.8446 percent, the value used in the FY 2017 IPPS final rule as the 2-year outlier threshold inflation factor, and 5.074 percent, the value used in the FY 2018 IPPS final rule as the 1-year outlier threshold inflation factor, to update the charges from FY 2015 to FY 2018. The applicant did not add charges for AndexXa™ as the price had not been set at the time of conducting this analysis. Under each scenario, the applicant stated that the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount (based on the FY 2018 IPPS Table 10 thresholds). Below we provide a table for all 12 scenarios that the applicant indicated demonstrate that the technology meets the cost criterion.

Scenario	Inflated average standardized case-weighted charge per case	Average case-weighted threshold amount
100 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	$71,305	$60,209
100 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	73,108	60,209
100 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	72,172	60,209
100 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	73,740	60,209
80 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	68,400	58,817
80 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	70,184	58,817
80 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	69,279	58,817
80 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	70,826	58,817
25 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Product Administration Costs	46,127	45,272
25 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Product Administration Costs	47,730	45,272
25 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Product Administration Costs	47,089	45,272
25 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Product Administration Costs	48,403	45,272

We are inviting public comments on whether AndexXa™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that AndexXa™ represents a substantial clinical improvement for the treatment of patients who are receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery because the technology addresses an unmet medical need for a universal antidote to direct and indirect Factor Xa inhibitors; if approved, would be the only agent shown in prospective clinical trials to rapidly (within 2 to 5 minutes) and sustainably reverse the anticoagulation activity of Factor Xa inhibitors; is potentially nonthrombogenic, as no serious adverse effects of thrombosis were observed in clinical trials; and could supplant currently available

treatments for bleeding from anti-Factor Xa therapy, which have not been shown to be effective in the treatment of all patients.

With regard to addressing an unmet need for a universal antidote to direct and indirect Factor Xa inhibitors, the applicant asserted that the use of any anticoagulant is associated with an increased risk of bleeding, and bleeding complications can be life-threatening. Bleeding is especially concerning for patients treated with Factor Xa inhibitors because there are currently no antidotes to Factor Xa inhibitors available. As a result, when a patient anticoagulated with an oral direct Factor Xa inhibitor presents with life-threatening bleeding, clinicians often resort to using preparations of vitamin K dependent clotting factors, such as 4-factor prothrombin complex concentrates (PCCs). Despite the lack of any large, prospective, randomized study examining the efficacy and safety of these agents in this patient population, administration of 4-factor PCCs as a means to ''reverse'' the anticoagulant effect of Factor Xa inhibitors is commonplace in many hospitals due to the lack of any alternative in the setting of a serious or life-threatening bleed.

The applicant stated that AndexXa™ has a unique mechanism of action and represents a new biological approach to the treatment of patients who have been diagnosed with acute severe bleeding who require immediate reversal of the Factor Xa inhibitor therapy. The applicant explained that although AndexXa™ is structurally very similar to native Factor Xa inhibitors, the technology has undergone several modifications that restrict its biological activity to reversing the effects of Factor Xa inhibitors by binding with and sequestering direct or indirect Factor Xa inhibitors, which allows native Factor Xa inhibitors to dictate the normal coagulation and hemostasis process. As a result, the applicant maintained that AndexXa™ represents a safe and effective therapy for the management of severe bleeding in a fragile patient population and a substantial clinical improvement over existing technologies and reversal strategies.

The applicant noted the following: (1) On average, patients with a bleeding complication were hospitalized for 6.3 to 8.5 days, and (2) the most common therapies currently used to manage severe bleeding events in patients undergoing anticoagulant treatment are blood and blood product transfusions, most frequently with packed red blood cells (RBC) or fresh frozen plasma (FFP).[238] According to the applicant, the blood products that are currently being employed as reversal agents carry significant risks. For instance, no clinical studies have evaluated the safety and efficacy of FFP transfusions to treat bleeding associated with Factor Xa inhibitors.[239] [240] Furthermore, transfusions with packed RBCs carry a risk (1 to 4 per 50,000 transfusions) of acute hemolytic reactions, in which the recipient's antibodies attack the transfused red blood cells, which is associated with clinically significant anemia, kidney failure, and death.[241] The applicant asserted that a RBC transfusion in trauma patients with major bleeding is associated with an increased risk of nonfatal vascular events and death.[242] The applicant noted that, although patients who are treated with AndexXa™ would receive RBC transfusions if their hemoglobin is low enough to warrant it, AndexXa™ reduces the need for RBC transfusion.

The applicant asserted that laboratory studies have failed to provide consistent evidence of ''reversal'' of the anticoagulant effect of Factor Xa inhibitors across a range of different PCC products and concentrations. Results of thrombin generation assays have varied depending on the format of the assay. Despite years of experience with low molecular weight heparins and pentasaccharide anticoagulants, neither PCCs nor factor eight inhibitor bypassing activity are recognized as safe and effective reversal agents for these Factor Xa inhibitors.[243] Unlike patients taking vitamin K antagonists, patients receiving treatment with oral Factor Xa inhibitor drugs have normal levels of clotting factors. Therefore, a strategy based on ''repleting'' factor levels is of uncertain foundation and could result in supra-normal levels of coagulation factors after rapid metabolism and clearance of the oral anticoagulant.[244]

The applicant provided results from two randomized, double-blind, placebo-controlled Phase III studies,[245] [246] the ANNEXA–A (reversal of apixaban) and ANNEXA-R (reversal of rivaroxaban) trials. The primary endpoint in both these studies was the percent change in anti-Factor Xa activity. Secondary endpoints included proportion of participants with an 80 percent or greater reduction in anti-Factor Xa activity, change in unbound Factor Xa inhibitor concentration, and change in endogenous thrombin potential (ETP). A total of 145 participants were enrolled in the study, with 101 participants randomized to AndexXa™ and 44 participants randomized to placebo. The mean age of participants was 58 years old, and 39 percent were women. There was a mean of greater than 90 percent reduction in anti-Factor Xa activity in both parts of both studies in subjects receiving AndexXa™. The studies also demonstrated the following: (1) Rapid and sustainable reversal of anticoagulation; (2) reduced Factor Xa inhibitor free plasma levels by at least 80 percent below a calculated no-effect level; and (3) reduced anti-Factor Xa activity to the lowest level of detection within 2 to 5 minutes of infusion. The applicant noted that decreased Factor Xa inhibitor levels have been shown to correspond to decreased bleeding complications, reconstitution of activity of coagulation factors, and correction of coagulation.[247] [248] [249]

The applicant stated that the results from the two Phase III studies and previous proof-of-concept Phase II dose-finding studies showed that use of

[238] Truven, ''2016 Truven Medicare Projected Bleeding Events'', MARKETSCAN® Medicare Supplemental Database, January 1, 2016 to December 31, 2016 Data pull, Data on File, Supplemental file.

[239] Siegal, D.M., ''Managing target-specific oral anticoagulant associated bleeding including an update on pharmacological reversal agents,'' *J Thromb Thrombolysis,* 2015 Apr, vol. 39(3), pp. 395–402.

[240] Kalus, J.S., ''Pharmacologic interventions for reversing the effects of oral anticoagulants,'' *Am J Health Syst Pharm,* 2013, vol. 70(10 Suppl 1), pp. S12–21.

[241] Sharma, S., Sharma, P., Tyler, L.N., ''Transfusion of Blood and Blood Products: Indications and Complications,'' *Am Fam Physician,* 2011, vol. 83(6), pp. 719–24.

[242] Perel, P., Clayton, T., Altman, D.G., et al., ''Red blood cell transfusion and mortality in trauma patients: risk-stratified analysis of an observational study,'' *PLoS Med,* 2014, vol. 11(6), pp. e1001664.

[243] Sarich, T.C., Seltzer, J.H., Berkowitz, S.D., et al., ''Novel oral anticoagulants and reversal agents: Considerations for clinical development,'' *Am Heart J,* 2015, vol. 169(6), pp. 751–7.

[244] Siegal, D.M., ''Managing target-specific oral anticoagulant associated bleeding including an update on pharmacological reversal agents,'' *J Thromb Thrombolysis,* 2015 Apr, vol. 39(3), pp. 395–402.

[245] Conners, J.M., ''Antidote for Factor Xa Anticoagulants,'' *N Engl J Med,* 2015 Nov 13.

[246] Siegal, D.M., Curnutte, J.T., Connolly, S.J., et al., ''Andexanet Alfa for the Reversal of Factor Xa Inhibitor Activity,'' *N Engl J Med,* 2015 Nov 11.

[247] Lu, G., DeGuzman, F., Hollenbach, S., et al., ''Reversal of low molecular weight heparin and fondaparinux by a recombinant antidote,'' (r-Antidote, PRT064445), *Circulation,* 2010, vol. 122, pp. A12420.

[248] Rose, M., Beasley, B., ''Apixaban clinical review addendum,'' Silver Spring, MD: Center for Drug Evaluation and Research, 2012. Available at: *http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202155Orig1s000MedR.pdf.*

[249] Beasley, N., Dunnmon, P., Rose, M., ''Rivaroxaban clinical review: FDA draft briefing document for the Cardiovascular and Renal Drugs Advisory Committee,'' 2011. Available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm270796.pdf.*

AndexXa™ can rapidly reverse anticoagulation activity of Factor Xa inhibitors and sustain that reversal. Therefore, the applicant asserted that the use of AndexXa™ has the potential to successfully treat patients who only need short-duration reversal of the Factor Xa inhibitor anticoagulant, as well as patients who require longer duration reversal, such as patients experiencing a severe intracranial hemorrhage or requiring emergency surgery. Furthermore, the applicant noted that its technology's duration of action allows for a gradual return of Factor Xa inhibitor concentrations to placebo control levels within 2 hours following the end of infusion.

With regard to AndexXa™'s nonthrombogenic nature, the applicant provided clinical trial data which revealed participants in Phase II and Phase III trials had no thrombotic events and there were no serious or severe adverse events reported. Results also showed that use of AndexXa™ has a much lower risk of thrombosis than typical procoagulants because the technology lacks the region responsible for inducing coagulation. Furthermore, the applicant asserted that the use of AndexXa™ is not associated with the known complications seen with RBC transfusions. The applicant asserted that, while the Phase II and Phase III trials and studies measured physiological hallmarks of reversal of NOACs, it is expected that the availability of a safe and reliable Factor Xa reversal will result in an overall better prognosis for patients—potentially leading to a reduction in length of hospital stay, fewer complications, and decreased mortality associated with unexpected bleeding episodes.

The applicant also stated that use of AndexXa™ can supplant currently available treatments used for reversing severe bleeding from anti-Factor Xa therapy, which have not been shown to be effective in the treatment of all patients. With regard to PCCs and FFPs, the applicant stated that there is a lack of clinical evidence available for patients taking Factor Xa inhibitors that experience severe bleeding events. The applicant noted that the case reports provide a snapshot of emergent treatment of these often medically complex anti-Factor Xa-treated patients with major bleeds. However, the applicant stated that these analyses reveal the inconsistent approach in assessing the degree of anticoagulation in the patient and the variability in treatment strategy. The applicant explained that little or no assessment of efficacy in restoring coagulation in the patients was performed, and the major outcomes measures were bleeding cessation or mortality. The applicant concluded that overall, there is very little evidence for the efficacy suggested in some guidelines, and the evidence is insufficient to draw any conclusions.

The applicant submitted interim data purporting to show substantial clinical improvement within its target patient population as part of an ongoing Phase IIIb/IV open-label ANNEXA–4 study. The ANNEXA–4 study is a multi-center, prospective, open-label, single group study that evaluated 67 patients who had acute, major bleeding within 18 hours of receipt of a Factor Xa inhibitor (32 patients receiving rivarobaxan, 31 receiving apixaban, and 4 receiving enoxaparin). The population in the study was reflective of a real-world population, with mean age of 77 years old, most patients with cardiovascular disease, and the majority of bleeds being intracranial or gastrointestinal. According to the applicant, the results of the ANNEXA–4 study demonstrate safe, reliable, and rapid reversal of Factor Xa levels in patients experiencing acute bleeding and are consistent with the results seen in the Phase II and Phase III trials, based on interim data. However, we are concerned that this interim data also indicate 18 percent of patients experienced a thrombotic event and 15 percent of patients died following reversal during the 30-day follow-up period in the ANNEXA–4 study. For this reason, we are concerned that there is insufficient data to determine substantial clinical improvement over existing technologies.

We are inviting public comments on whether AndexXa™ meets the substantial clinical improvement criterion.

We did not receive any public comments on the AndexXa™ technology in response to the published notice in the **Federal Register** or at the New Technology Town Hall Meeting.

III. Proposed 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 2019 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.) 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 2019 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 2019 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 2019 wage index appears under sections III.E.3. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed FY 2019 Hospital Wage Index

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 on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the OMB labor market 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 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB Web site at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.* We note that we did not have sufficient time to include this change in the computation of the proposed FY 2019 wage index, ratesetting, and Tables 2 and 3 associated with this proposed rule. This new CBSA may affect the budget neutrality factors and wage indexes, depending on whether the area is eligible for the rural floor and the impact of the overall payments of the hospital located in this new CBSA. We are providing below an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 wage index (described below in section III.B. of the preamble of this proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

Below in sections III.D. and E.2. of the preamble of this proposed rule, we provide the proposed FY 2019 unadjusted and occupational mix adjusted national average hourly wages. Taking the estimated average hourly wage of new CBSA 46300 and dividing by the proposed national average hourly wage results in the estimated wage indexes shown in the table below.

	Estimated unadjusted wage index for new CBSA 46300	Estimated occupational mix adjusted wage index for new CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

For FY 2019, we are using the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01. In the final rule, we will incorporate this change into the final FY 2019 wage index, ratesetting, and tables.

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. The updated changes were 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 2019, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2019, 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 2019 Wage Index

The proposed FY 2019 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2015 (the FY 2018 wage indexes were based on data from cost reporting periods beginning during FY 2014).

1. Included Categories of Costs

The proposed FY 2019 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 2018, the proposed wage index for FY 2019 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 2019 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).

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.

C. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2019 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) for cost reporting periods beginning on or after October 1, 2014, and before October 1, 2015. For wage index purposes, we refer to cost reports during this period as the ''FY 2015 cost report,'' the ''FY 2015 wage data,'' or the ''FY 2015 data.'' Instructions for completing the wage index sections of Worksheet S-3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2019 wage index includes FY 2015 data submitted to us as of February 6, 2018. 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 2019 wage index, we identified and excluded 80 providers with aberrant data that should not be included in the wage index, although if data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2019 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 23, 2018. In addition, as a result of the April and May appeals processes, and posting of the April 27, 2018 PUF, we may make additional revisions to the FY 2019 wage data, as described further below. The revised data would be reflected in the FY 2019 IPPS/LTCH PPS final rule.

In constructing the proposed FY 2019 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2015, 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 believed that 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 this proposed

rule, we removed 8 hospitals that converted to CAH status on or after January 23, 2017, the cut-off date for CAH exclusion from the FY 2018 wage index, and through and including January 26, 2018, the cut-off date for CAH exclusion from the FY 2019 wage index. After excluding CAHs and hospitals with aberrant data, we calculated the proposed wage index using the Worksheet S–3, Parts II and III wage data of 3,260 hospitals.

For the proposed FY 2019 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2018 wage index (82 FR 38131 through 38132); that is, 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 2019 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:

CSA certification number (CCN) of multicampus hospital	Full-time equivalent (FTE) percentages
050121	0.81
05B121	0.19
070022	0.99
07B022	0.01
070033	0.92
07B033	0.08
100029	0.54
10B029	0.46
100167	0.37
10B167	0.63
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
330234	0.72
33B234	0.28
360019	0.95
36B019	0.05
360020	0.99
36B020	0.01
390006	0.95
39B006	0.05
390115	0.86
39B115	0.14
390142	0.83
39B142	0.17
460051	0.97
46B051	0.03
510022	0.95
51B022	0.05
670062	0.55
67B062	0.45

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 this proposed rule and future rulemaking, 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 2019 Unadjusted Wage Index

1. Proposed Methodology for FY 2019

The method used to compute the proposed FY 2019 wage index without an occupational mix adjustment follows the same methodology that we used to compute the proposed wage indexes without an occupational mix adjustment since FY 2012 (76 FR 51591 through 51593).

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, 2014, through April 15, 2016, 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 2019. 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
10/14/2014	11/15/2014	1.02567
11/14/2014	12/15/2014	1.02413
12/14/2014	01/15/2015	1.02257
01/14/2015	02/15/2015	1.02100
02/14/2015	03/15/2015	1.01941
03/14/2015	04/15/2015	1.01784
04/14/2015	05/15/2015	1.01627
05/14/2015	06/15/2015	1.01471
06/14/2015	07/15/2015	1.01316
07/14/2015	08/15/2015	1.01161
08/14/2015	09/15/2015	1.01007
09/14/2015	10/15/2015	1.00849
10/14/2015	11/15/2015	1.00685
11/14/2015	12/15/2015	1.00516
12/14/2015	01/15/2016	1.00343
01/14/2016	02/15/2016	1.00171
02/14/2016	03/15/2016	1.00000
03/14/2016	04/15/2016	0.99824

For example, the midpoint of a cost reporting period beginning January 1, 2015, and ending December 31, 2015, is June 30, 2015. An adjustment factor of 1.01316 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as previously described, the proposed FY 2019 national average hourly wage (unadjusted for occupational mix) is $42.990625267.

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, 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 calculated a Puerto Rico-specific wage index that was applied to the labor 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) (which is $42.990625267 for this FY 2019 proposed rule) and the national wage index, which is applied to the national labor share of the national standardized amount. For FY 2019, we

are not proposing a Puerto Rico-specific overall average hourly wage or wage index.

2. Proposed Update of Policies Related to Other Wage-Related Costs, Clarification of the Calculation of Other Wage-Related Costs, and Proposals for FY 2020 and Subsequent Years

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index based on a survey of hospitals' costs that are attributable to wages and wage-related costs. In the September 1, 1994 IPPS final rule (59 FR 45356), we developed a list of ''core'' wage-related costs that hospitals may report on Worksheet S–3, Part II of the Medicare hospital cost report in order to include those costs in the wage index. Core wage-related costs include categories of retirement cost, plan administrative costs, health and insurance costs, taxes, and other specified costs such as tuition reimbursement.

In addition to these categories of core wage-related costs, we allow hospitals to report wage-related costs other than those on the core list if the other wage-related costs meet certain criteria. The criteria for including other wage-related costs in the wage index are discussed in the September 1, 1994 IPPS final rule (59 FR 45357) and clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38132 through 38136). In addition, the criteria for including other wage-related costs in the wage index are listed in the Provider Reimbursement Manual (PRM), Part II, Chapter 40, Sections 4005.2 through 4005.4, Line 18 on W/S S–3 Part II and Line 25 and its subscripts on W/S S–3 Part IV of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38132 through 38136), we clarified that a hospital may be able to report a wage-related cost (defined as the value of the benefit) that does not appear on the core list if it meets all of the following criteria:

- The wage-related cost is provided at a significant financial cost to the employer. To meet this test, the individual wage-related cost must be greater than 1 percent of total salaries after the direct excluded salaries are removed (the sum of Worksheet S–3, Part II, Lines 11, 12, 13, 14, Column 4, and Worksheet S–3, Part III, Line 3, Column 4).
- The wage-related cost is a fringe benefit as described by the IRS and is reported to the IRS on an employee's or contractor's W–2 or 1099 form as taxable income.
- The wage-related cost is not furnished for the convenience of the provider or otherwise excludable from income as a fringe benefit (such as a working condition fringe).

We noted that those wage-related costs reported as salaries on Line 1 (for example, loan forgiveness and sick pay accruals) should not be included as other wage-related costs on Line 18.

The above instructions for calculating the 1-percent test inadvertently omitted Line 15 for Home Office Part A Administrator on Worksheet S–3, Part II from the denominator. Line 15 should be included in the denominator because Home Office Part A Administrator is added to Line 1 in the wage index calculation. Therefore, in this proposed rule, we are correcting the inadvertent omission of Line 15 from the denominator, and we are clarifying that, for calculating the 1-percent test, each individual category of the other wage-related cost (that is, the numerator) should be divided by the sum of Worksheet S–3, Part III, Lines 3 and 4, Column 4 (that is, the denominator). Line 4 sums the following lines from Worksheet S–3, Part II: Lines 11, 12, 13, 14, 14.01, 14.02, and 15. We also direct readers to instructions for calculating the 1-percent test in the Provider Reimbursement Manual (PRM), Part II, Chapter 40, Section 4005.4, Line 25 and its subscripts on Worksheet S–3, Part IV of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050), which state: ''Calculate the 1-percent test by dividing each individual category of the other wage-related cost (that is, the numerator) by the sum of Worksheet S–3, Part III, Lines 3 and 4, Column 4, (that is, the denominator).''

In addition to our discussion about calculating the 1-percent test and other criteria for including other-wage related costs in the wage index, we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38133 through 38166) that we would consider proposing to remove other wage-related costs from the wage index entirely.

In the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 19901 and 82 FR 38133, respectively), we stated that we originally allowed for the inclusion of wage-related costs other than those on the core list because we were concerned that individual hospitals might incur unusually large wage-related costs that are not reflected on the core list but that may represent a significant wage-related cost. However, we stated in the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 19901 and 82 FR 38133, respectively) that we were reconsidering allowing other wage-related costs to be included in the wage index because internal reviews of the FY 2018 wage data showed that only a small minority of hospitals were reporting other wage-related costs that meet the 1-percent test described earlier.

This year, as part of the wage index desk review process for FY 2019, internal reviews showed that only 8 hospitals out of the more than 3,000 IPPS hospitals in the wage index had other wage-related costs that were correctly reported for inclusion in the wage index. Given the extremely limited number of hospitals nationally using Worksheet S–3, Part IV, Line 25 and subscripts, and Worksheet S–3, Part II, Line 18, to correctly report other wage-related costs in accordance with the criteria to be included in the wage index, we continue to believe that other wage-related costs do not constitute an appropriate and significant portion of wage costs in a particular labor market area. In other words, while other wage-related costs may represent costs that may have an impact on an *individual* hospital's average hourly wage, we do not believe that costs reported by only a very small minority of hospitals (less than 0.003 percent) accurately reflect the economic conditions of the labor market area as a whole in which such an individual hospital is located. The fact that only 8 hospitals out of more than 3,000 IPPS hospitals included in the FY 2019 IPPS proposed wage index reported other wage-related costs correctly in accordance with the 1-percent test and related criteria indicates that, in fact, other wage-related costs are *not* a relative measure of the labor costs to be included in the IPPS wage index. Therefore, we believe that inclusion of other wage-related costs in the wage index in such a limited manner may distort the average hourly wage of a particular labor market area so that its wage index does not accurately represent that labor market area's current wages relative to national wages.

Furthermore, the open-ended nature of the types of other wage-related costs that may be included on Line 25 and its subscripts of Worksheet S–3 Part IV and Line 18 of Worksheet S–3 Part II, in contrast to the concrete list of core wage-related costs, may hinder consistent and proper reporting of fringe benefits. Our internal reviews indicate widely divergent types of costs that hospitals are reporting as other wage-related costs on these lines. We are concerned that inconsistent reporting of other wage-related costs further compromises the accuracy of the wage index as a representation of the relative average hourly wage for each labor

market area. Our intent in creating a core list of wage-related costs in the September 1, 1994 IPPS final rule was to promote consistent reporting of fringe benefits, and we are increasingly concerned that inconsistent reporting of wage-related costs undermines this effort. Specifically, we expressed in the September 1, 1994 IPPS final rule that, since we began including fringe benefits in the wage index, we have been concerned with the inconsistent reporting of fringe benefits, whether because of a lack of provider proficiency in identifying fringe benefit costs or varying interpretations across fiscal intermediaries of the definition for fringe benefits in PRM–I, Section 2144.1 (59 FR 45356). We believe that the limited and inconsistent use of Line 25 and its subscripts of Worksheet S–3 Part IV and Line 18 of Worksheet S–3 Part II for reporting wage-related costs other than the core list indicate that including other wage-related costs in the wage index compromises the accuracy of the wage index as a relative measure of wages in a given labor market area.

Therefore, for the reasons discussed earlier, for the FY 2020 wage index and subsequent years, we are proposing to only include the wage-related costs on the core list in the calculation of the wage index and not to include any other wage-related costs in the calculation of the wage index. Under our proposal, we would no longer consider any other wage-related costs beginning with the FY 2020 wage index. Considering the extremely limited number of hospitals reporting other wage-related costs and the inconsistency in types of other wage-related costs being reported, we believe this proposal will help ensure a more consistent and more accurate wage index representative of the relative average hourly wage for each labor market area. In addition, we believe that this proposal to no longer include other wage-related costs in the wage index calculation benefits the vast majority of hospitals because most hospitals do not report other wage-related costs. Because the wage index is budget neutral, hospitals in an area without other wage-related costs included in the wage index have their wage indexes reduced when other areas' wage indexes are raised by including other wage-related costs in their wage index calculation. We also note that this proposal to exclude other wage-related costs from the wage index, starting with the FY 2020 wage index, contributes to agency efforts to simplify hospital paperwork burden because it would eliminate the need for Line 18 on Worksheet S–3, Part II and Line 25 and its subscripts on Worksheet S–3, Part IV of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050). We note that we would include in the FY 2019 wage index the other wage-related costs of the eight hospitals that accurately reported those costs in accordance with the current criteria.

In summary, we are clarifying that our current policy for calculating the 1-percent test includes Line 15 for Home Office Part A Administrator on Worksheet S–3, Part II in the denominator. In addition, we are proposing to eliminate other wage-related costs from the calculation of the wage index for the FY 2020 wage index and subsequent years, as discussed earlier. We are inviting public comments on this proposal.

3. Proposals To Codify Policies Regarding Multicampus Hospitals

We have received an increasing number of inquiries regarding the treatment of multicampus hospitals as the number of multicampus hospitals has grown in recent years. While the regulations at § 412.230(d)(2)(iii) and (v) for geographic reclassification under the MGCRB include criteria for how multicampus hospitals may be reclassified, the regulations at § 412.92 for sole community hospitals (SCHs), § 412.96 for rural referral centers (RRC), § 412.103 for rural reclassification, and § 412.108 for Medicare-dependent, small rural hospitals (MDHs) do not directly address multicampus hospitals. Thus, in this proposed rule, we are proposing to codify in these regulations the policies for multicampus hospitals that we have developed in response to recent questions regarding CMS' treatment of multicampus hospitals for purposes other than geographic reclassification under the MGCRB.

The proposals below apply to hospitals with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meet the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, also referred to as multicampus hospitals or hospitals with remote locations. We are proposing that a main campus of a hospital cannot obtain an SCH, RRC, or MDH status or rural reclassification independently or separately from its remote location(s), and vice versa. Rather, if the criteria are met in the regulations at § 412.92 for SCHs, § 412.96 for RRCs, § 412.103 for rural reclassification, or § 412.108 for MDHs (as discussed later in this section), the hospital (that is, the main campus and its remote location(s)) would be granted the special treatment or rural reclassification afforded by the aforementioned regulations.

We believe this is an appropriate policy for two reasons. First, each remote location of a hospital is included on the main campus's cost report and shares the same provider number. That is, the main campus and remote location(s) would share the same status or rural reclassification because the hospital is a single entity with one provider agreement. Second, it would not be administratively feasible for CMS and the MACs to track every hospital with remote locations within the same CBSA and to assign different statuses or rural reclassifications exclusively to the main campus or to its remote location. We note that, for wage index purposes only, CMS tracks multicampus remote locations located *in different CBSAs* in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). However, for purposes of rural reclassification under § 412.103, we do not believe it would be appropriate for a main campus and remote location(s) (whether located in the same or separate CBSAs) to be reclassified independently or separately from each other because, unlike MGCRB reclassifications which are used only for wage index purposes, § 412.103 rural reclassifications have payment effects other than wage index (for example, payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA).

To qualify for rural reclassification or SCH, RRC, or MDH status, we are proposing that a hospital with remote locations must demonstrate that both the main campus and its remote location(s) satisfy the relevant qualifying criteria. A hospital with remote locations submits a joint cost report that includes data from its main campus and remote location(s), and its MedPAR data also combine data from the main campus and remote location(s). We believe that it would not be feasible to separate data by location, nor would it be appropriate, because we consider a main campus and remote location(s) to be one hospital. Therefore, where the regulations at § 412.92, § 412.96, § 412.103, and § 412.108 require data, such as bed count, number of discharges, or case-mix index, for example, to demonstrate that the hospital meets the qualifying criteria, we are proposing to codify in our regulations that the combined data from the main campus and its remote location(s) are to be used.

For example, if a hospital with a main campus with 200 beds and a remote location with 75 beds applies for RRC status, the combined count of 275 beds would be considered the hospital's bed count, and the main campus and its remote location would be granted RRC status if the hospital applies during the last quarter of its cost reporting period and both the main campus and the remote location are located in a rural area as defined in 42 CFR part 412, subpart D. This is consistent with the regulation at § 412.96(b)(1), which states, in part, that the number of beds is determined under the provisions of § 412.105(b). For § 412.105(b), beds are counted from the main campus and remote location(s) of a hospital. We believe this is also consistent with § 412.96(b)(1)(ii), which sets forth the criteria that the hospital is located in a rural area and the hospital has a bed count of 275 or more beds during its most recently completed cost reporting period, unless the hospital submits written documentation with its application that its bed count has changed since the close of its most recently completed cost reporting period for one or more of several reasons, *including the merger of two or more hospitals.*

Similarly, combined data would be used for demonstrating the hospital meets criteria at § 412.92 for SCH status. For example, the patient origin data, which are typically MedPAR data used to document the boundaries of the hospital's service area as required in § 412.92(b)(1)(ii) and (iii), would be used from both locations. We reiterate that we believe this is the appropriate policy because the main campus and remote location are considered one hospital and that it is the only administratively feasible policy because there is currently no way to split the MedPAR data for each location.

For § 412.103 rural reclassification, a hospital with remote location(s) seeking to qualify under § 412.103(a)(3), which requires that the hospital would qualify as an RRC or SCH if the hospital were located in a rural area, would similarly demonstrate that it meets the criteria at § 412.92 or at § 412.96, such as bed count, by using combined data from the main campus and its remote location(s) (with the exception of certain criteria discussed below related to location, mileage, travel time, and distance requirements). We refer readers to the portions of our discussion that explain how hospitals with remote locations would meet criteria for RRC or SCH status.

A hospital seeking MDH status would also use combined data for bed count and discharges to demonstrate that it meets the criteria at § 412.108(a)(1). For example, if the main campus of a hospital has 75 beds and its remote location has 30 beds, the bed count exceeds 100 beds and the hospital would not satisfy the criteria at § 412.108(a)(1)(i) (which is proposed to be redesignated as 412.108(a)(1)(ii)).

We are reminding readers that, under § 412.108(b)(4) and § 412.92(b)(3)(i), an approved MDH or SCH status determination remains in effect unless there is a change in the circumstances under which the status was approved. While we believe that this proposal is consistent with the policies for multicampus hospitals that we have developed in response to recent questions, current MDHs and SCHs should make sure that this proposal does not create a change in circumstance (such as an increase in the number of beds to more than 100 for MDHs or to more than 50 for SCHs), which an MDH or SCH is required to report to the MAC within 30 days of the event, in accordance with § 412.108(b)(4)(ii) and (iii) and § 412.92(b)(3)(ii) and (iii).

With regard to other qualifying criteria set forth in the regulations at §§ 412.92, 412.96, 412.103, and 412.108 that do not involve data that can be combined, specifically qualifying criteria related to location, mileage, travel time, and distance requirements, a hospital would need to demonstrate that the main campus and its remote location(s) each independently satisfy those requirements in order for the entire hospital, including its remote location(s), to be reclassified or obtain a special status.

To qualify for SCH status, for example, it would be insufficient for only the main campus, and not the remote location, to meet distance criteria. Rather, the main campus and its remote location(s) would each need to meet at least one of the criteria at § 412.92(a). Specifically, the main campus and its remote location must each be located more than 35 miles from other like hospitals, or if in a rural area (as defined in § 412.64), be located between 25 and 35 miles from other like hospitals if meeting one of the criteria at § 412.92(a)(1) (and each meet the criterion at § 412.92(a)(1)(iii) if applicable), or between 15 and 25 miles from other like hospitals if the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years (§ 412.92(a)(2)), or travel time to the nearest like hospital is at least 45 minutes (§ 412.92(a)(3)). We believe that this is necessary to show that the hospital is indeed the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under Medicare Part A, as required by section 1886(d)(5)(D)(iii)(II) of the Act. For hospitals with remote locations that apply for SCH classification under § 412.92(a)(1)(i) and (ii), combined data are used to document the boundaries of the hospital's service area using data from across both locations, as discussed earlier, and all like hospitals within a 35-mile radius of each location are included in the analysis. To be located in a rural area to use the criteria in § 412.92(a)(1), (2), and (3), the main campus and its remote location(s) must each be either geographically located in a rural area, as defined in § 412.64, or reclassified as rural under § 412.103.

Similarly, for RRC classification under § 412.96 and MDH classification under § 412.108, the main campus and its remote location(s) must each be either geographically located in a rural area, as defined in 42 CFR part 412, subpart D, or reclassified as rural under § 412.103 to meet the rural requirement portion of the criteria at § 412.96(b)(1), § 412.96(c), or § 412.108(a)(1) (or for MDH, be located in a State with no rural area and satisfy any of the criteria under § 412.103(a)(1) or (a)(3) or under § 412.103(a)(2) as of January 1, 2018). For hospitals with remote locations that apply for RRC classification under § 412.96(b)(2)(ii) or § 412.96(c)(4), 25 miles is calculated from each location (the main campus and its remote location(s)), and combined data from both the main campus and its remote location(s) are used to calculate the percentage of Medicare patients, services furnished to Medicare beneficiaries, and discharges.

For hospitals seeking to reclassify as rural by meeting the criteria at § 412.103(a)(1), (a)(2), or (a)(6), we also are proposing to codify in our regulations that it would not be sufficient for only the main campus, and not its remote location(s), to demonstrate that its location meets the aforementioned criteria. Rather, under § 412.103(a)(1) and (2) (which also are incorporated in § 412.103(a)(6)), we are proposing that the main campus and its remote location(s) must each either be located (1) in a rural census tract of an MSA as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area codes (§ 412.103(a)(1)), or (2) in an area designated by any law or regulation of the State in which it is located as a rural area, or be designated as a rural hospital by State law or regulation (§ 412.103(a)(2)). For hospitals seeking to reclassify as rural

by meeting the criteria in § 412.103(a)(3), which require that the hospital would qualify as an RRC or a SCH if the hospital were located in a rural area, we refer readers to our discussion presented earlier that explains how hospitals with remote locations would meet criteria for RRC or SCH status.

We note that we have also received questions about how a hospital with remote locations that trains residents in approved medical residency training programs would be treated for IME adjustment purposes if it reclassifies as rural under § 412.103. As we noted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50114), the rural reclassification provision of § 412.103 only applies to IPPS hospitals under section 1886(d) of the Act. Therefore, it applies for IME payment purposes, given that the IME adjustment under section 1886(d)(5)(B) of the Act is an additional payment under IPPS. In contrast, sections 1886(a)(4) and (d)(1)(A) of the Act exclude direct GME costs from operating costs and these costs are not included in the calculation of the IPPS payment rates for inpatient hospital services. Payment for direct GME is separately authorized under section 1886(h) of the Act and, therefore, not subject to § 412.103. Therefore, if a geographically urban teaching hospital reclassifies as rural under § 412.103, such a reclassification would only affect the teaching hospital's IME adjustment, and not its direct GME payment. Accordingly, we are clarifying that in order for the IME cap adjustment regulations at § 412.105(f)(1)(iv)(A), § 412.105(f)(1)(vii), and § 412.105(f)(1)(xv) to be applicable to a teaching hospital with a main campus and a remote location(s), the main campus and its remote location(s), respectively, must each be either geographically located in a rural area as defined in 42 CFR part 412, subpart D, or reclassified as rural under § 412.103. For direct GME purposes at § 413.79, both the main campus and its remote location(s) are required to be geographically rural because a hospital's status for any direct GME payments or adjustments is unaffected by a § 412.103 rural reclassification.

We are proposing to codify these policies regarding the application of the qualifying criteria for hospitals with remote locations in the regulations at § 412.92 for SCHs, § 412.96 for RRCs, § 412.103 for rural reclassification, or § 412.108 for MDHs. Specifically, we are proposing to revise these regulations as follows:

We are proposing to add paragraph (a)(4) to § 412.92 to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria at § 412.92(a)(1)(i) and (ii) are met. For the mileage and rural location criteria at § 412.92(a) and the mileage, accessibility, and travel time criteria specified at § 412.92(a)(1) through (a)(3), the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

In § 412.96, we are proposing to redesignate paragraph (d) as paragraph (e) and add a new paragraph (d) to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria at § 412.96(b)(1) and (2) and (c)(1) through (c)(5) are met. For purposes of meeting the rural location criteria in § 412.96(b)(1) and (c) and the mileage criteria in § 412.96(b)(2)(ii) and (c)(4), the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

We are proposing to add paragraph (a)(7) to § 412.103 to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy the location criteria specified in § 412.103(a)(1) and (2) (which criteria also are incorporated in § 412.103(a)(6)).

We are proposing to add paragraph (a)(3) to § 412.108 to specify that, for a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the IPPS and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria in § 412.108(a)(1) and (2) are met. For the location requirement specified at proposed amended paragraph (a)(1)(i) of this section, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy this requirement.

We are inviting public comments on our proposals described above.

E. Proposed Occupational Mix Adjustment to the FY 2019 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 Proposed FY 2019 Wage Index

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. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), a new measurement of occupational mix is required for FY 2019.

The FY 2019 occupational mix adjustment is based on a new calendar year (CY) 2016 survey. Hospitals were required to submit their completed 2016 surveys (Form CMS–10079, OMB number 0938–0907) 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 2019 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that result in certain edit failures.

2. Calculation of the Proposed Occupational Mix Adjustment for FY 2019

For FY 2019, 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 2019 wage index. 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 2019 occupational mix adjusted wage index, includes separate wage data for the campuses of 16 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 2019 wage index. For the proposed FY 2019 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,260 hospitals, and we are using the occupational mix surveys of 3,078 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 94 percent (3,078/3,260). For the proposed FY 2019 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 2019 occupational mix adjusted national average hourly wage is $42.948428861.

In summary, the proposed FY 2019 unadjusted national average hourly wage and the proposed FY 2019 occupational mix adjusted national average hourly wage is:

Proposed unadjusted national average hourly wage	Proposed occupational mix adjusted national average hourly wage
$42.990625267	$42.948428861

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2019 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2019, we are proposing to apply the occupational mix adjustment to 100 percent of the FY 2019 wage index. We calculated the proposed 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). Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2019 wage index results in a proposed national average hourly wage of $42.948428861.

The proposed FY 2019 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	$41.67064907
National LPN and Surgical Technician	24.68950438
National Nurse Aide, Orderly, and Attendant	16.96671421
National Medical Assistant	18.1339666
National Nurse Category	35.05256013

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $35.05256013. 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 42.3 percent, and the national percentage of hospital employees in the all other occupations category is 57.7 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 26.6 percent in one CBSA to a high of 82.0 percent in another CBSA.

We compared the FY 2019 proposed occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. As a result of applying the proposed occupational mix adjustment to the wage data, the proposed wage index values for 232 (56.9 percent) urban areas and 23 (48.9 percent) rural areas would increase. The proposed wage index values for 113 (27.7 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and the proposed wage index values for 7 (1.7 percent) urban areas would increase by 5 percent or more. The proposed wage index values for 9 (19.1 percent) rural areas would increase by greater than or equal to 1 percent but less than 5 percent, and 1 rural area's proposed wage index value would increase by 5 percent or more. However, the proposed wage index values for 175 (42.9 percent) urban areas and 24 (51.1 percent) rural areas would decrease. The proposed wage index values for 81 (19.9 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and 1 urban area's proposed wage index value would decrease by 5 percent or more. The proposed wage index values of 6 (12.8 percent) rural areas would decrease by greater than or equal to 1 percent and less than 5 percent, and no rural areas' proposed wage index values would decrease by 5 percent or more. The largest proposed positive impacts would be 6.42 percent for an urban area and 5.25 percent for a rural area. The largest proposed negative impacts would be 5.84 percent for an urban area and 1.6 percent for a rural area. One urban area's proposed wage indexes, but no rural area proposed wage indexes, would remain unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of urban areas (56.9 percent) would benefit from the occupational mix adjustment than would rural areas (48.9 percent).

We also compared the FY 2019 wage data adjusted for occupational mix from the 2016 survey to the FY 2019 wage data adjusted for occupational mix from the 2013 survey. This analysis illustrates the effect on area wage indexes of using the 2016 survey data compared to the 2013 survey data; that is, it shows whether hospitals' wage indexes would increase or decrease under the 2016 survey data as compared to the prior 2013 survey data. Of the 407

urban CBSAs and 47 rural CBSAs, our analysis shows that the FY 2019 wage index values for 179 (43.9 percent) urban areas and 20 (42.6 percent) rural areas would increase using the 2016 survey data. Ninety-eight (24.0 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and 27 (6.6 percent) urban areas would increase by 5 percent or more. Nine (19.1 percent) rural areas would increase by greater than or equal to 1 percent but less than 5 percent, and 4 (8.5 percent) rural areas would increase by 5 percent or more. However, the wage index values for 229 (56.1 percent) urban areas and 27 (57.4 percent) rural areas would decrease using the 2016 survey data. One hundred thirty three (32.6 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and 24 (5.9 percent) urban areas would decrease by 5 percent or more. Eleven (23.4 percent) rural areas would decrease by greater than or equal to 1 percent but less than 5 percent, and 2 (4.3 percent) rural areas would decrease by 5 percent or more. The largest positive impacts using the 2016 survey data compared to the 2013 survey data are 17.2 percent for an urban area and 13.8 percent for a rural area. The largest negative impacts are 13.0 percent for an urban area and 14.0 percent for rural areas. No urban areas and no rural areas are unaffected. These results indicate that the wage indexes of more CBSAs overall (56.3 percent) would decrease due to application of the 2016 occupational mix survey data as compared to the 2013 occupational mix survey data to the wage index. Further, a slightly larger percentage of urban areas (43.9 percent) would benefit from the use of the 2016 occupational mix survey data as compared to the 2013 occupational mix survey data than would rural areas (42.6 percent).

G. Proposed Application of the Rural, Imputed, and Frontier Floors

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 proposed FY 2019 wage index associated with this proposed rule (which is available via the Internet on the CMS website), we estimated that 255 hospitals would receive an increase in their FY 2019 proposed wage index due to the application of the rural floor.

2. Proposed Expiration of Imputed Floor Policy

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy eight times, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and is set to expire on September 30, 2018. (We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FY 2014 through FY 2018 (78 FR 50589 through 50590, 79 FR 49969 through 49970, 80 FR 49497 through 49498, 81 FR 56921 through 56922, and 82 FR 38138 through 38142, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States—Delaware, New Jersey, and Rhode Island—with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation. (We refer readers to discussions of geographic reclassifications and redesignations in section III.I. of the preamble of this proposed rule.)

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI–MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS website) included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to

explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor. As discussed in section III.B. of the preamble of that FY 2015 final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI-MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49497 through 49498), for FY 2016, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56921 through 56922), for FY 2017, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2017. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142), for FY 2018, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2018. In these three final rules, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the additional 1-year extensions.

The imputed floor is set to expire effective October 1, 2018, and in this FY 2019 proposed rule, we are not proposing to extend the imputed floor policy. In the FY 2005 IPPS final rule (69 FR 49110), we adopted the imputed floor policy for all-urban States under the authority of section 1886(d)(3)(E) of the Act, which gives the Secretary broad authority to adjust 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 for area differences in hospital wage levels by a factor (established by the Secretary). However, we have expressed reservations about the establishment of an imputed floor, considering that the imputed rural floor methodology creates a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor (72 FR 24786 and 72 FR 47322). As we discussed in the FY 2008 IPPS final rule (72 FR 47322), the application of the rural and imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. For this reason, in this proposed rule, we are proposing not to apply an imputed floor to wage index calculations and payments for hospitals in all-urban States for FY 2019 and subsequent years. That is, hospitals in New Jersey, Delaware, and Rhode Island (and in any other all-urban State) would receive a wage index that is calculated without applying an imputed floor for FY 2019 and subsequent years. Therefore, only States containing both rural areas and hospitals located in such areas (including any hospital reclassified as rural under the provisions of § 412.103 of the regulations) would benefit from the rural floor, in accordance with section 4410 of Public Law 105–33. In addition, we would no longer include the imputed floor as a factor in the national budget neutrality adjustment. Therefore, the proposed wage index and impact tables associated with this FY 2019 IPPS/LTCH PPS proposed rule (which are available via the Internet on the CMS website) do not reflect the imputed floor policy, and there is no proposed national budget neutrality adjustment for the imputed floor for FY 2019.

We are inviting public comments on our proposal not to extend the imputed floor for FY 2019 and subsequent years.

3. Proposed State Frontier Floor for FY 2019

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 2019 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2019. In this proposed rule, 50 hospitals would receive the frontier floor value of 1.0000 for their FY 2019 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

The areas affected by the proposed rural and frontier floor policies for the proposed FY 2019 wage index are identified in Table 2 associated with this proposed rule, which is available via the Internet on the CMS website.

H. Proposed FY 2019 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). In addition, as discussed in section III.J. of the preamble of this proposed rule, we are adding a Table 4 associated with this proposed rule entitled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019'' (which is available via Internet on the CMS Website) We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the proposed wage index tables for FY 2019.

I. 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). 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. 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.

2. MGCRB Reclassification and Redesignation Issues for FY 2019

a. FY 2019 Reclassification 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 2019 reclassification requests. Based on such reviews, there are 337 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2019. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2019, hospitals reclassified beginning in FY 2017 or FY 2018 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 259 hospitals approved for wage index reclassifications in FY 2017 that will continue for FY 2019, and 345 hospitals approved for wage index reclassifications in FY 2018 that will continue for FY 2019. Of all the hospitals approved for reclassification for FY 2017, FY 2018, and FY 2019, based upon the review at the time of this proposed rule, 941 hospitals are in a MGCRB reclassification status for FY 2019 (with 22 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).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2019 will be incorporated into the wage index values published in the FY 2019 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

Applications for FY 2020 reclassifications (OMB control number 0938–0573) are due to the MGCRB by September 4, 2018 (the first working day of September 2018). We note that this is also the deadline for canceling a previous wage index reclassification, withdrawal, or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2018, via the Internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html,* or by calling the MGCRB at (410) 786-1174. The mailing address of the MGCRB is: 1508 Woodlawn Drive, Suite 100, Baltimore, MD 21207.

Under regulations in effect prior to FY 2018 (42 CFR 412.256(a)(1)), applications for reclassification were required to be mailed or delivered to the MGCRB, with a copy to CMS, and were not allowed to be submitted through the facsimile (FAX) process or by other electronic means. Because we believed this previous policy was outdated and overly restrictive and to promote ease of application for FY 2018 and subsequent years, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we revised this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS. Specifically, in the FY 2017 IPPS/LTCH PPS final rule, we revised § 412.256(a)(1) to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an

electronic copy of the application sent to CMS. We specified that CMS copies should be sent via email to *wageindex@cms.hhs.gov.*

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928), we reiterated that MGCRB application requirements will be published separately from the rulemaking process, and paper applications will likely still be required. The MGCRB makes all initial determinations for geographic reclassification requests, but CMS requests copies of all applications to assist in verifying a reclassification status during the wage index development process. We stated that we believed that requiring electronic versions would better aid CMS in this process, and would reduce the overall burden upon hospitals.

b. Proposed Revision of Reclassification Requirements for a Provider That Is the Sole Hospital in the MSA

Section 412.230 of the regulations sets forth criteria for an individual hospital to apply for geographic reclassification to a higher rural or urban wage index area. Specifically, under § 412.230(a)(1)(ii), an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to an urban area for the purpose of using the other area's wage index value. Such a hospital must also meet other criteria. One of these required criteria, under § 412.230(d)(1)(iii)(C), is that the hospital must demonstrate that its own average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent, and in the case of a hospital located in an urban area, at least 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located. We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48568) for further explanation as to how the 108/106 percent average hourly wage standards were determined. In cases in which a hospital wishing to reclassify is the only hospital in its MSA, that hospital is unable to satisfy this criterion because it cannot demonstrate that its average hourly wage is higher than that of the other hospitals in the area in which the hospital is located (because there are no other hospitals in the area).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51600 through 51601), we implemented a policy change to allow for waiver of the average hourly wage comparison criterion under § 412.230(d)(1)(iii) for a hospital in a single hospital MSA for reclassifications beginning in FY 2013 if the hospital could document that it is the single hospital in its MSA that is paid under 42 CFR part 412, subpart D (§ 412.230(d)(5)). In that final rule, we stated that we agreed that the then-current policies for geographic reclassification were disparate for hospitals located in single hospital MSAs compared to hospitals located in multiple hospital MSAs. We also acknowledged commenters' views that this disparity was sometimes a disadvantage because hospitals in single hospital MSAs had fewer options for qualifying for geographic reclassification. In the years since we implemented this policy change, we have encountered questions and concerns regarding its implementation. Currently, to qualify under § 412.230(d)(5) for the waiver of the average hourly wage criterion under § 412.230(d)(1)(iii)(C), a hospital must document to the MGCRB that it is the only hospital in its geographic wage index area that is paid under 42 CFR part 412, subpart D. To do so, a hospital frequently is required to contact the appropriate CMS Regional Office or MAC for a statement certifying its status as the single hospital in its MSA. Hospitals have indicated that this process may be time-consuming, inconsistent in its application nationally, and poses challenges with respect to accurately reflecting situations where hospitals have recently opened or ceased operations during the application process. In light of these questions and concerns and after reviewing the implementation of this reclassification provision, we believe that a revision of the policy is necessary to reduce unnecessary burden to affected hospitals and enhance consistency while achieving previously stated policy goals.

The objective of the 108/106 percent average hourly wage criterion at § 412.230(d)(1)(iii)(C) is to require a reclassifying hospital to document that it has significantly higher average hourly wages than other hospitals in its labor market area. The stated purpose of § 412.230(d)(5) was to provide additional reclassification options for hospitals that, due to their single hospital MSA status, could not mathematically meet the requirements of § 412.230(d)(1)(iii). Therefore, in order to determine whether a hospital is the single hospital in the MSA under § 412.230(d)(5), rather than require the hospital to obtain documentation from the CMS Regional Office or the MAC to prove its single hospital MSA status, we believe it would be appropriate to use the same data used to determine whether the 108/106 percent criterion is met under § 412.230(d)(1)(iii)(C): That is, the annually published 3-year average hourly wage data as provided in § 412.230(d)(2)(ii). Specifically, in this proposed rule, we are proposing that, for reclassification applications for FY 2021 and subsequent fiscal years, a hospital would provide the wage index data from the current year's IPPS final rule to demonstrate that it is the only hospital in its labor market area with wage data listed within the 3-year period considered by the MGCRB. Accordingly, we are proposing to revise the regulation text at § 412.230(d)(5) to provide that the requirements of § 412.230(d)(1)(iii) would not apply if a hospital is the single hospital in its MSA with published 3-year average hourly wage data included in the current fiscal year inpatient prospective payment system final rule. In proposing this revision, we would remove the language in this regulation requiring that the hospital be the single hospital ''paid under subpart D of this part'', as we believe the proposed revisions to the regulation above more accurately identify the universe of hospitals this policy was intended to address. That is, to meet the requirements of a single hospital MSA, we are proposing that a hospital applying for reclassification beginning in FY 2021 (application that is due September 1, 2019) must only provide documentation from Table 2 of the Addendum to the FY 2020 IPPS/LTCH PPS final rule demonstrating it is the only CCN listed within the associated ''Geographic CBSA'' numbers (currently listed under column H) with a ''3-Year Average Hourly Wage (2018, 2019, 2020)'' value (currently listed under column G).

The purpose of the single hospital MSA provision was to address situations where a hospital essentially had no means of comparing wages to other hospitals in it labor market area. We believe this proposal would allow for a more straightforward and consistent implementation of the single hospital MSA exception and would reduce provider burden. We believe the proposed requirements above for meeting the single hospital MSA exception can be easily verified and validated by the applicant and the MGCRB, and would continue to address the concerns expressed by commenters included in the FY 2012 IPPS/LTCH PPS final rule.

We are inviting public comments on this proposal, which, if finalized, would be effective for reclassifications beginning in FY 2021.

c. Clarification of Group Reclassification Policies for Multicampus Hospitals

Under current policy described in §§ 412.230(d)(2)(v), 412.232(d)(2)(iii), and 412.234(c)(2), and as discussed in the FY 2008 IPPS/LTCH final rule (72 FR 47334 through 47335), remote locations of hospitals in a distinct geographic area from the main hospital campus are eligible to seek wage index reclassification. In Table 2 associated with this proposed rule (which is available via the Internet on the CMS website), such locations are indicated with a ''B'' in the third digit of the CCN. (As discussed in section III.C. of the preamble of this proposed rule, in past years, the ''B'' was instead placed in the fourth digit.) When CMS initially includes such a ''B'' hospital location in Table 2 for a particular fiscal year, it signifies that, for wage index purposes, the hospital indicated the presence of a remote location in a distinct geographic area on Worksheet S–2 of the cost report used to construct that current fiscal year's wage index, and hours and wages were allocated between the main campus and the remote location. For billing purposes, these ''B'' locations are assigned their own area wage index value, separate from the main hospital campus. Hospitals are eligible to seek both individual and county group reclassifications for these ''B'' locations through the MGCRB, using the wage data published for the most recent IPPS final rule for the ''B'' location. While we are not proposing any change to the multicampus hospital reclassification policy, it has come to our attention that the MGCRB has had difficulty processing certain county group reclassification applications that include multicampus locations that have not yet been assigned a ''B'' number in Table 2. Typically, this would occur when an inpatient hospital location has recently been opened or acquired, creating a new ''B'' location. Because the wage index development process utilizes cost reports that end up to 4 years prior to the upcoming IPPS fiscal year, the most recently published wage data for the hospital used to construct the wage index would not reflect the specific wage data for any new ''B'' location in a different labor market area. However, as specified in §§ 412.232(a)(2) and 412.234(a)(1) of the regulations, for county group reclassification applications, all hospitals in a county must apply for reclassification as a group. Thus, in order for hospitals in a county to obtain reclassification as a group, these new ''B'' locations are required under these regulations to be a party to any county group reclassification application, despite not having wage data published in Table 2. In a group reclassification involving a new ''B'' location, the ''B'' location would not yet have data included in the CMS hospital survey used to construct the wage index and to evaluate reclassification requests, and the most recently published wage data of the main hospital would encompass a time period well before the creation or acquisition of the new remote location. Therefore, the hospital could not submit composite average hourly wage data for the ''B'' location with the county group reclassification application. Because the county group reclassification application must list all active hospitals located in the county of the hospital group, including any ''B'' locations, if a ''B'' number is not listed in Table 2 associated with the IPPS final rule used to evaluate reclassification criteria, we are requesting that the county hospital group submit the application listing the remote location with a ''B'' in the third digit of the hospital's CCN to help facilitate the MGCRB's review. If the county group reclassification is approved by the MGCRB, CMS will include the hospital's ''B'' location in Table 2 of the subsequent IPPS final rule, and will instruct the MAC to adjust the payment for that remote location to the appropriate reclassified area. This ''B'' location designation would be included in subsequent rules, without composite wage data, until a time when the wage data of the new location are included in the cost report used to construct the wage index in effect for IPPS purposes, and a proper allocation can be determined.

3. Redesignations Under Section 1886(d)(8)(B) of the Act

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 out-migration 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 again clarified that such a request to waive Lugar status, received within 45 days of the publication of the proposed rule, is valid for the full 3-year period for which the hospital's out-migration adjustment is effective. 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.

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 out-migration 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, 2017, and 2018 IPPS/LTCH PPS final rules (80 FR 49501, 81 FR 56930, and 82 FR 38150, respectively), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FY 2016, FY 2017 and FY 2018, and we are proposing to use them again for FY 2019. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2019. 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 2019, 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 2019, 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 2019 wage index.

In addition, we are adding a new Table 4, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019,''associated with this proposed rule. This table consists of the following: a list of counties that would be eligible for the out-migration adjustment for FY 2019 identified by FIPS county code, the proposed FY 2019 out-migration adjustment, and the number of years the adjustment would be in effect. We believe this new table would make this information more transparent and provide the public with easier access to this information. We intend to make the information available annually via Table 4 in the IPPS/LTCH PPS proposed and final rules, and are including it among the tables associated with this FY 2019 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 and Proposed Change to 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.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. There may be one or more reasons that a hospital applies for the urban to rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). 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, after notice of proposed rulemaking and consideration of public comments, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (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), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date (the lock-in date) must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for a full discussion of this policy.

In this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to change the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline. As we discussed in the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25071 and 56931, respectively), the IPPS ratesetting process that CMS undergoes each proposed and final rulemaking is complex and labor-intensive, and subject to a compressed timeframe in order to issue the final rule each year within the timeframes for publication. Accordingly, CMS must ensure that it receives, in a timely fashion, the necessary data, including, but not limited to, the list of hospitals that are reclassified from urban to rural status under § 412.103, in order to calculate the wage indexes and other IPPS rates.

In order to allot more time to the ratesetting process, we are proposing to revise the lock-in date such that a hospital's application for rural reclassification under § 412.103 must be approved by the CMS Regional Office

no later than 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register 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), (e)(4), and (h) for payment rates for the next Federal fiscal year. Depending on the public display date of the proposed rule (which may be earlier in future years), this proposed revision to the lock-in date would potentially allow for additional time in the ratesetting process for CMS to incorporate rural reclassification data, which we believe would support efforts to eliminate errors and assist in ensuring a more accurate wage index.

Under this proposed revision, there would no longer be a requirement that the hospital file its rural reclassification application by a specified date (which under the current policy is 70 days prior to the second Monday in June). While we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930 through 56932) that a hospital would need to file its reclassification application with the CMS Regional Office not later than 70 days prior to the second Monday in June, that timeframe was a precautionary measure to ensure that CMS would receive the approval in time to include the reclassified hospitals in the wage index and budget neutrality calculations for the upcoming Federal fiscal year (60 days for the CMS Regional Office to approve an application, in accordance with § 412.103(c), and an additional 10 days to process the approval and notify CMS Central Office). While we still believe that it would be prudent for hospitals to apply approximately 70 days prior to the proposed lock-in date, we believe that requiring hospitals to apply by a set date is unnecessary because the Regional Offices may approve a hospital's request to reclassify under § 412.103 in less than 60 days, and CMS may be notified in a timeframe shorter than 10 days. Therefore, under our proposal, any hospital with an approved rural reclassification by the lock-in date proposed above (that is, 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register) would be included in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, regardless of the date of filing.

In addition, we note that CMS generally provides 60 days after the public display date of the IPPS notice of proposed rulemaking at the Office of the Federal Register for submitting public comments regarding the proposed rule for consideration in the final rule. Therefore, we believe that, in addition to providing for more time in the ratesetting process, which helps to ensure a more accurate wage index, this proposed revision would also provide clarity and simplify regulations by synchronizing the lock-in date for § 412.103 redesignations with the usual public comment deadline for the IPPS proposed rule.

Accordingly, we are proposing to revise § 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), (e)(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. We are inviting public comments on this proposal.

We are reiterating that 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), 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.

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 for the proposed FY 2019 wage index were made available on May 19, 2017, and the preliminary CY 2016 occupational mix data files were made available on July 12, 2017, through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items-FY-2019-Wage-Index-Home-Page.html.*

On February 2, 2018, we posted a public use file (PUF) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items-FY-2019-Wage-Index-Home-Page.html* containing FY 2019 wage index data available as of February 1, 2018. 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 l, 2014 through September 30, 2015; that is, FY 2015 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 February 2, 2018 wage data PUF, and a tab containing the CY 2016 occupational mix data of the hospitals deleted from the February 2, 2018 occupational mix PUF. In a memorandum dated December 14, 2017, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the February 2, 2018 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2019 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 Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html.*

In a memorandum dated April 28, 2017, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files posted on May 19, 2017, and the process and timeframe for requesting revisions. The preliminary CY 2016 occupational mix survey data was posted on CMS' website on July 12, 2017.

If a hospital wished to request a change to its data as shown in the May 19, 2017 preliminary wage data files and the July 12, 2017 preliminary occupational mix data files, the hospital had to submit corrections along with

complete, detailed supporting documentation to its MAC by September 1, 2017. 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, 2017 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 4, 2017 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 2018. CMS published the wage index PUFs that included hospitals' revised wage index data on February 2, 2018. Hospitals had until February 16, 2018, to submit requests to the MACs to correct errors in the February 2, 2018 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 February 2, 2018 PUF. Hospitals also were required to submit sufficient documentation to support their requests.

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 23, 2018. 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 5, 2018. Data that were incorrect in the preliminary or February 2, 2018 wage index data PUFs, but for which no correction request was received by the February 16, 2018 deadline, are not considered for correction at this stage. In addition, April 5, 2018 is the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified after the February 2, 2018 PUF and at least 14 calendar days prior to April 5, 2018 (that is, March 22, 2018), that do not arise from a hospital's request for revisions. We note that, as we did for the FY 2018 wage index, for the proposed FY 2019 wage index, in accordance with the FY 2019 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items-FY-2019-Wage-Index-Home-Page.html,* the April appeals have to be sent via mail and email. 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-FY2019-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 2015 data used to construct the proposed FY 2019 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 2018.

We plan to post the final wage index data PUFs in late April 2018 via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items-FY-2019-Wage-Index-Home-Page.html.* The April 2018 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 23, 2018, 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 2018 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 23, 2017.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 2, 2018 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 2018 final wage index data PUFs, a hospital believes that its wage or occupational mix data were 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 no later than May 30, 2018. May 30, 2018 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 5, 2018 (that is, March 23, 2018), and at least 14 calendar days prior to May 30, 2018 (that is, May 16, 2018), 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 30, 2018 (that is, May 17, 2018) may be appealed to the Provider Reimbursement Review Board (PRRB)). Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2019 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items-FY-2019-Wage-Index-Home-Page.html,* 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 30, 2018) by CMS and the MACs will be incorporated into the final FY 2019 wage index, which will be effective October 1, 2018.

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 2019 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 set forth above (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 requested 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 2018, 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 2019 wage index by August 2018, and the implementation of the FY 2019 wage index on October 1, 2018. 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 30, 2018, 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 30, 2018 for the FY 2019 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 30, 2018 deadline for the FY 2019 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 30, 2018 deadline for the FY 2019 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 February 2 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.M.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 February 2 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.D.2. of the preamble of this FY 2019 IPPS/LTCH PPS proposed rule, in the calculation of the proposed FY 2019 wage index, upon discovering that hospitals reported other wage-related costs on Line 18 of Worksheet S-3, despite those other wage-related costs failing to meet the requirement that other wage-related costs must exceed 1 percent of total adjusted salaries net of excluded area salaries, CMS made internal edits to remove those other wage-related costs from Line 18. Conversely, 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), starting with the FY 2019 wage index, we implemented a process for hospitals 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 February 2 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) bring additional transparency to instances where CMS makes data corrections after the February 2 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 2019 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 8156).

M. Proposed Labor-Related Share for the Proposed FY 2019 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 which 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.

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 2019, 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 2019, we are proposing to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2018.

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 2019, 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 2019 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 2019, 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 2019, we are proposing to apply the wage index to a proposed labor-related share of 68.3 percent of the national standardized amount.

We are inviting public comments on our proposals discussed above.

N. Request for Public Comments on Wage Index Disparities

CMS is committed to transforming the health care delivery system, including the Medicare program, by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We are seeking to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible.

One key to that transformation is ensuring that the Medicare payment rates are as accurate and appropriate as possible, consistent with the law. As described later in this section, there have been numerous studies, analyses, and reports on disparities between the wage index values for individual hospitals and the wage index values among different geographic areas and ways to improve the Medicare wage index. Given that some time has elapsed since these studies were performed, in this proposed rule, we are taking this opportunity to invite the public to submit further comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index that address these issues. If practicable, we are requesting the public to submit appropriate supporting data and specific recommendations in their comments. For any suggestions or recommendations presented that involve novel legal questions, we welcome analysis regarding CMS' authority for our consideration.

1. General Background

As we discussed earlier, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must 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. Section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section of the Act provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. Section 1886(d)(3)(E) of the Act also requires us to make any updates or adjustments to the wage index for a fiscal year in a manner that ensures that aggregate payments to hospitals in a fiscal year are not greater or less than those that would have been made in the year without the wage index adjustment.

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) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions.

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. For this purpose, the statute requires the exclusion of data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility services.

The current wage index methodology relies on labor markets that are based on statistical area definitions (CBSAs) established by OMB. Hospitals are grouped by geographic location into either an urban labor market (that is, an MSA or metropolitan division) or a statewide rural labor market (any area of a State that is not defined as urban). The current system also relies on hospital wage data submitted by hospitals to CMS, rather than on data that reflect broader labor market wages such as data from the Bureau of Labor Statistics or data from the American Community Survey. In public comments received on prior rulemaking for FYs 2009, 2010, and 2011, many parties have argued that the current labor market definitions and wage data sources used by CMS, in many instances, are not reflective of the true cost of labor for any given hospital or are inappropriate to use for this purpose, or both. (These public comments (on proposed rules under file numbers CMS–1390–P, CMS–1406–P, and CMS–1498–P) are available via the Internet on the website at: *www.regulations.gov.*) For responses to public comments received on the FY 2009 IPPS/LTCH PPS proposed rule, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48563 through 48567); for responses to public comments on the FY 2010 IPPS/LTCH PPS proposed rule, we refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43824 through 43826); and for responses to public comments on the FY 2011 IPPS/LTCH PPS proposed rule, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50157 through 50160).) With respect to the labor market definitions, multiple exceptions and adjustments (for example, provider reclassifications under the MGCRB and the rural floor adjustment) have been put into place in attempts to correct perceived inequities. However, many of these exceptions and adjustments may create or further exacerbate distortions in labor market values. The issue of ''cliffs,'' or significant differences in wage index values between proximate hospitals, can often be attributed to one hospital benefiting from such an exception and adjustment when another hospital cannot. With respect to the wage data sources, in public comments on prior proposed rulemakings cited earlier, many stakeholders have argued that the use of hospital reported data results in increasing wage index disparities over time between high wage index areas and low wage index areas. (These public comments are available via the Internet on the website at: *www.regulations.gov.*)

2. Prior Reports, Studies, and Analyses

a. MedPAC Report to Congress

Section 106(b)(1) of the Medicare Improvements and Extension Act of 2006, Division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA), Public Law 109–432, required MedPAC to submit to Congress, not later than June 30, 2007, a report on the Medicare wage index classification system applied under the Medicare

prospective payment systems, including the IPPS under section 1886(d)(3)(E) of the Act. Section 106(b) of MIEA–TRHCA required the report to include any alternatives that MedPAC recommends to the method to compute the wage index under section 1886(d)(3)(E) of the Act.

In addition, section 106(b)(2) of the MIEA–TRHCA instructed the Secretary of Health and Human Services, taking into account MedPAC's recommendations on the Medicare wage index classification system, to include in the FY 2009 IPPS proposed rule one or more proposals to revise the wage index adjustment applied under section 1886(d)(3)(E) of the Act for purposes of the IPPS. The Secretary was also directed to consider each of the following:

- Problems associated with the definition of labor markets for the wage index adjustment;
- The modification or elimination of geographic reclassifications and other adjustments;
- The use of Bureau of Labor of Statistics (BLS) data or other data or methodologies to calculate relative wages for each geographic area;
- Minimizing variations in wage index adjustments between and within MSAs and statewide rural areas;
- The feasibility of applying all components of CMS' proposal to other settings;
- Methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality;
- The effect that the implementation of the proposal would have on health care providers and on each region of the country;
- Methods for implementing the proposal(s), including methods to phase in such implementations; and
- Issues relating to occupational mix, such as staffing practices, and any evidence on the effect on quality of care and patient safety, including any recommendation for alternative calculations to the occupational mix.

In its June 2007 Report to Congress, ''Report to the Congress: Promoting Greater Efficiency in Medicare'' (Chapter 6 with Appendix), MedPAC made three broad recommendations regarding the wage index:

(1) Congress should repeal the existing hospital wage index statute, including reclassifications and exceptions, and give the Secretary authority to establish a new wage index system.

(2) The Secretary should establish a hospital compensation index that—

- Uses wage data from all employers and industry-specific occupational weights;
- Is adjusted for geographic differences in the ratio of benefits to wages;
- Is adjusted at the county level and smooths large differences between counties; and
- Is implemented so that large changes in wage index values are phased in over a transition period.

(3) The Secretary should use the hospital compensation index for the home health and skilled nursing facility prospective payment systems and evaluate its use in the other Medicare fee-for-service prospective payment systems.

Following are the highlights of the alternative wage index system recommended by MedPAC:

- The MedPAC recommended wage index generally retains the current labor market definitions but supplements the metropolitan areas with county-level adjustments and eliminates single wage index values for rural areas.
- In the MedPAC recommended wage index, the county-level adjustments, together with a smoothing process that constrains the magnitude of differences between and within contiguous wage areas, serve as a replacement for geographical reclassifications.
- The MedPAC recommended wage index uses BLS data instead of the CMS hospital wage data collected on the Medicare cost report. MedPAC adjusts the BLS data for geographic differences in the ratio of benefits to wages using Medicare cost report data.
- The BLS data are collected from a sample of all types of employers, not just hospitals. The MedPAC recommended wage index could be adapted for other providers, such as home health agencies and skilled nursing facilities by replacing hospital occupational weights with occupational weights appropriate for other types of providers.
- In the MedPAC recommended wage index, volatility over time is addressed by the use of BLS data, which is based on a 3-year rolling sample design.
- MedPAC recommended a phased implementation for its recommended wage index in order to cushion the effect of large wage index changes on individual hospitals.
- MedPAC suggested that using BLS data automatically addresses occupational mix differences because the BLS data are specific to health care occupations and national industry-wide occupational weights are applied to all geographic areas.

The full June 2007 MedPAC Report to Congress is available at the MedPAC website site: *http://medpac.gov/docs/default-source/reports/Jun07_EntireReport.pdf.*

During the FY 2009 IPPS rulemaking process, we received many public comments regarding MedPAC's recommendations for reforming the wage index (73 FR 48564 through 48566). The public comments varied greatly, and there was no consensus position among the commenters. A complete set of the public comments on the FY 2009 IPPS proposed rule (CMS–1390–P) is available via the Internet on the website at: *www.regulations.gov.*

In the FY 2009 IPPS final rule (73 FR 48564 through 48567), we also summarized an analysis of MedPAC's recommendations that was performed by our contractor, Acumen LLC. In that analysis, we used a variety of terminology to refer to the wage indexes recommended by MedPAC, as well as the wage indexes currently used by CMS:

- When we referred to MedPAC's ''hospital compensation index'' or ''compensation index'', we were discussing the wage index that MedPAC developed that includes an adjustment to account for differences in the ratio of benefits to wages in different labor market areas. MedPAC developed this ratio of benefits using Medicare cost report data.
- When we referred to MedPAC's recommended ''wage index'', we were discussing the MedPAC-developed index without any adjustment for nonwage benefits. This wage index was developed using BLS data.
- When we referred to CMS' ''pre-reclassification wage index'' or ''pre-reclassification, pre-floor wage index'', we were discussing the wage index developed by CMS but without any adjustments for geographic reclassifications or the rural floor. This wage index also does not include any adjustments for outmigration, section 508 reclassifications, Lugar redesignations, section 401 urban-to-rural reclassifications, or for any special exceptions.
- When we referred to CMS' ''final wage index'', we were discussing the wage index developed by CMS that is the final wage index received by or to be received by a hospital. Thus, this wage index does account for all geographic reclassifications as well as the rural floor. This final wage index also includes any adjustments as a result of outmigration, section 508 reclassifications, Lugar redesignations, section 401 urban-to-rural

reclassifications, or any other special exceptions.

Acumen analyzed and compared all four of the wage indexes cited above. In other words, Acumen compared (A) CMS' pre-reclassification, pre-floor wage index for FY 2008 (which was provided by CMS and is based on hospital cost reports from FY 2004) and CMS' final wage index for FY 2008 with (B) both the MedPAC recommended hospital compensation index and wage index for FY 2007. Acumen's comparisons of the CMS wage index to the MedPAC recommended indexes indicate the effects of various components of the alternative wage indexes. All of the comparisons reflect differences between the CMS and BLS wage data. The comparison of the CMS pre-reclassification index to the MedPAC hospital compensation index reflects the additional impact of MedPAC's method of using county-level adjustors to smooth differences in index values among the CMS wage areas. The comparison of the CMS pre-reclassification index to the MedPAC recommended wage index includes the effect of county-level smoothing and indicates the incremental effect of removing the MedPAC adjustment for benefits. The comparison of the CMS final wage index to the MedPAC recommended wage index adds the incremental effect of geographic reclassifications and other wage index exceptions (for example, the rural and imputed floors) to the preceding comparison. Finally, the comparison of the CMS final wage index to the MedPAC recommended compensation index yields the combined effects of all the differences between the two indexes.

First, Acumen analyzed the overall impacts of the MedPAC recommended indexes. Acumen conducted the analysis at two levels: The hospital level and the county level. At the hospital level, Acumen analyzed all four comparisons described above. However, at the county level, Acumen did not include comparisons using the CMS final wage index because it includes reclassifications and other changes that are granted to hospitals, not counties. As a result, hospitals in the same county or wage area can have different final wage index values. Acumen's analysis was based on 3,426 hospitals, for which all four wage index values were available (the CMS pre-reclassification wage index, the CMS final wage index, the MedPAC recommended hospital wage index, and the MedPAC recommended hospital compensation index), and on the 1,595 counties in which these hospitals are located.

Second, Acumen estimated the impact for several subgroups of hospitals and counties. At the hospital level, Acumen assessed the impact by geographic area (for example, urban hospitals and rural hospitals), hospital size (number of beds), geographic region, teaching status, DSH status, SCH status, RRC status, MDH status, type of ownership (government, proprietary, voluntary), and reclassification status. At the county level, Acumen presented results for metropolitan area counties and rural counties.

Third, Acumen calculated the change in the wage index that each hospital (or county) could expect to experience from adopting the MedPAC recommendations and reported statistics on these expected differences (mean, median, standard deviation, minimum, and maximum). Acumen did not model changes in Medicare payments that would result from using different wage indexes. Instead, Acumen normalized all four wage indexes by setting their discharge weighted means equal to 1.00. Normalization puts all four wage indexes on the same scale so that differences in wage index values between one index and another index are directly comparable. As a result, the wage index differences reported by Acumen imply payment differences, but do not precisely measure the magnitude of those payment differences.

The main findings of Acumen's impact analysis are summarized as follows:

- Adopting the MedPAC recommendations would reduce the differentials between wage index values across geographic areas. Both the MedPAC wage and compensation indexes are less dispersed than either the CMS pre-reclassification wage index or the final wage index.
- Under either of the MedPAC recommended indexes, differences between the highest wage index hospitals and the lowest wage index hospitals would be reduced. For example, the range or difference that exists from the highest wage index hospital to the lowest wage index hospital (the ''high-low range'') under the MedPAC compensation index (0.752 versus 1.499, or a difference of 0.747) is roughly 11 percent less than the high-low range under the CMS final wage index (0.732 versus 1.569, or a difference of 0.837). Using the CMS pre-reclassification wage index as a comparison (with a high-low range of 0.716 versus 1.600), the MedPAC recommended compensation index is roughly 16 percent less. The minimum value of the MedPAC recommended compensation index (0.752) is roughly 5 percent more than the minimum value of the CMS pre-reclassification wage index (0.716), and the maximum value of the MedPAC recommended compensation index (1.499) is roughly 6 percent less than the maximum value of the CMS pre-reclassification index (1.600).
- Adopting the MedPAC recommendations would also lower the wage dispersion among both rural hospitals and urban hospitals (whether classified by geography or payment), among hospitals of all sizes, and among all hospitals categorized by teaching status, DSH status, ownership status, and Medicare utilization status. These findings are generally consistent, regardless of whether the MedPAC recommended compensation index is compared to the CMS final wage index or to the CMS pre-reclassification wage index.
- Adopting the MedPAC recommendations would have a differential impact on urban hospitals across geographic regions of the country. In moving from the CMS final wage index to the MedPAC compensation index, the largest reduction in standard deviations would occur for urban hospitals in the New England region (−19.0 percent), the Middle Atlantic region (−27.8 percent), and the Pacific region (−19.0 percent). However, for urban hospitals in the West North Central region, the standard deviation of wage index values would increase by 11.7 percent.
- Adopting the MedPAC recommendations would decrease the standard deviation among hospitals with most types of reclassifications. For example, compared to the CMS final wage index, the MedPAC compensation index would reduce the standard deviation by 11.6 percent.
- The adoption of the MedPAC recommended indexes would lead a substantial number of hospitals to experience a large change in their index values in the transition. If the MedPAC compensation index is compared to the CMS final wage index, 37 percent of all hospitals would experience either increases or decreases of more than 5 percent. For approximately 34 percent of the reclassified hospitals (or 278 hospitals), wage index values would decrease by more than 5 percent. Reclassified hospitals comprise more than one-half of all hospitals that would likely experience wage index decreases greater than 5 percent in moving from the CMS final wage index to the MedPAC compensation index.
- Under a move from the CMS pre-reclassification wage index to the MedPAC recommended compensation

index, counties in rural areas would experience fewer decreases and more increases in their wage index compared to counties in urban areas. (As noted earlier, county-level comparisons were not performed using the CMS final wage index.)

The full Acumen analysis of the MedPAC recommendations (Impact Analysis for the 2009 Final Rule: Interim Report—Revision of Medicare Wage Index) is available via the Internet on the website at: *http://www.acumenllc.com/reports/cms.*

b. Acumen Report on Revision of the Medicare Wage Index

In addition to the analysis of the MedPAC recommendation that Acumen performed, in the FY 2010 and FY 2011 IPPS rulemaking (74 FR 43824 through 48325 and 75 FR 50158 through 50159, respectively), we discussed a separate report by Acumen on the wage index and methodology entitled ''Revision of the Medicare Wage Index'' (available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*). The report was divided into two parts. The first part analyzed the strengths and weaknesses of the data sources used to construct the MedPAC and CMS indexes. The second part focused on the methodology of wage index construction and covered issues related to the definition of wage areas and methods of adjusting for differences among neighboring wage areas, as well as reasons for differential impacts of shifting to a new index.

Specifically, in the first part of the report, Acumen examined the following issues:

- *Differences between the BLS data and the CMS wage data*—Acumen assessed the strengths and weaknesses of the data used to construct the CMS wage index and the MedPAC compensation index by examining the differences between the BLS and the CMS wage data. Acumen also evaluated the importance of accounting for self-employed workers, part-time workers, and industry wage differences.
- *Employee benefit (wage-related) cost*—Acumen considered whether benefit costs need to be included in the hospital wage index and discussed the differences between the Medicare cost report Worksheet A benefits data (proposed by MedPAC to use with BLS wage data) and the Medicare cost report Worksheet S–3 benefit data. Acumen also analyzed the possibility of using BLS' Employer Costs for Employee Compensation (ECEC) series as an alternative to Worksheet A or Worksheet S–3 benefits data that would pose less of a data collection burden for providers.
- *Impact of the fixed national occupational weights*—Acumen assessed MedPAC's and CMS' methods for adjusting for occupational mix differences. While the MedPAC recommended compensation index uses fixed weights for occupations representative of the hospital industry nationally, the CMS wage index incorporates an occupational mix adjustment from a separate data collection.
- *Year-to-year volatility in the CMS and BLS wage data*—Acumen calculated the extent of volatility in the CMS and BLS wage indexes using several measures of volatility. Acumen also explored potential causes of volatility, such as the number of hospitals and the annual change in the number of hospitals in a wage area. Finally, Acumen evaluated the impact on annual volatility of using a 2-year rolling average of CMS wage index values.

Acumen concluded that MedPAC's recommended methods for revising the wage index represent an improvement over the existing methods, and that the BLS data should be used so that the MedPAC approach can be implemented.

Several commenters during the FY 2010 and FY 2011 IPPS rulemakings (74 FR 43824 and 75 FR 50158, respectively) reiterated their concerns regarding the use of the BLS data for computing the Medicare wage index that they had expressed in public comments on the FY 2009 IPPS final rule (73 FR 48564 through 48565). The commenters stated that they still had significant concerns about the shortcomings of the BLS data, and they urged CMS to move cautiously in considering MedPAC's and Acumen's findings. Other commenters expressed support for MedPAC's and Acumen's findings and recommendations, although some commenters cautioned that a few refinements may still be needed before adopting these recommendations.

The second part of Acumen's final report focused on the methodology of wage index construction and covered issues related to the definition of wage areas and methods of adjusting for differences among neighboring wage areas, as well as reasons for differential impacts of shifting to a new index. In particular, the second part of the report provides a more in-depth analysis of MedPAC's recommended method of improving upon the definition of the wage areas used in the current wage index. MedPAC's method first blends MSA and county-level wages and then implements a ''smoothing'' step that limits differences in wage index values between adjacent counties to no more than 10 percent. Acumen found MedPAC's method to be an improvement over the current wage index construction. Acumen recommended further exploration of labor market area definitions using a wage area framework based on hospital-specific characteristics, such as commuting times from hospitals to population centers, to construct a more accurate hospital wage index. Acumen suggested that such an approach offers the greatest potential for replacing or greatly reducing the need for hospital reclassifications and exceptions.

We received many public comments regarding the Acumen analysis (75 FR 50158 through 50159). Again, the public comments varied greatly, and there was no consensus position among the commenters. One national hospital association in its comments recommended that CMS consider the following guiding principles as it evaluates options for improving the wage index system: Any new system should—

- Be fair and accurately reflect the labor marketplace for hospitals, for example, consider only hospital wage and benefit costs rather than broader labor market costs;
- Provide predictable payments;
- Be stable;
- Be transparent so that the data may be examined and verified;
- Minimize the administrative burden on hospitals;
- Utilize the most current information possible;
- Define boundaries that capture meaningful relationships between labor markets, to reduce the need for exceptions and reclassifications;
- Due to the imperfection of any current labor market definition that we are aware of, provide an exception process for hospitals with labor costs atypical for areas to which they have been assigned;
- Use consistent definitions, methodologies, rules, and interpretations across the nation for the acquisition and application of data;
- Include a transition from the old to the new system that is not disruptive; it should include a phased-in transition period if necessary to protect hospitals from abrupt reductions in payment levels; and
- Not let perfection be the enemy of the better.

Commenters generally urged CMS to move forward cautiously and ensure a thorough process for evaluating changes to the existing wage index.

The complete sets of the public comments on the FY 2010 IPPS/LTCH PPS proposed rule (CMS–1406–P) and the FY 2011 IPPS/LTCH PPS proposed rule (CMS–1498–P) are available via the Internet on the website at: *www.regulations.gov.*

c. Report to Congress—Plan To Reform the Medicare Hospital Wage Index

Section 3137(b) of the Affordable Care Act required the Secretary of Health and Human Services to submit to Congress, not later than December 31, 2011, a report that includes a plan to reform the Medicare wage index applied under the Medicare IPPS. In developing the plan, the Secretary had to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 report, including establishing a new system that—

- Uses BLS data, or other data or methodologies, to calculate relative wages for each geographic area;
- Minimizes wage index adjustments between and within MSAs and statewide rural areas;
- Includes methods to minimize the volatility of wage index adjustments while maintaining budget neutrality in applying such adjustments;
- Takes into account the effect that implementation of the system would have on health care providers and on each region of the country;
- Addresses issues related to occupational mix, such as staffing practices and ratios, and any evidence on the effect on quality of care or patient safety as a result of the implementation of the system; and
- Provides for a transition.

After we consulted with relevant parties during the development of the plan (which included an April 12, 2011 special wage index reform open door forum, along with a review of electronically submitted comments and concerns), the Secretary submitted a Report to Congress—Plan to Reform the Medicare Hospital Wage Index on April 11, 2012 that describes the concept of a Commuting Based Wage Index (CBWI) as one potential replacement for the current Medicare wage index methodology. Acumen again assisted CMS is the analysis for the report. The following is a summary of the highlights of the report:

The report included a potential change in the description and definition of labor market areas. The concept, referred to as the CBWI, would use commuting data to define hospital labor market areas. The CBWI is based on data on the number of hospital workers commuting from home to work to define a hospital's labor market. To derive the CBWI, commuting flows would be used to identify the specific areas (for example, zip code or census tracts) from which a hospital hires its workers and to determine the proportion of its workers hired from each area. A CBWI system could use either current hospital cost report data or other alternative sources, such as the BLS Occupational Employment Survey data, to calculate labor market area average wage values. While the current wage index system aggregates wage data within geographic CBSA-based areas where hospitals are located, the CBWI would aggregate wage data based upon where the hospital workers reside.

Once the hiring proportions by area and area wage levels are determined, the hospital's benchmark wage level would be calculated as the weighted average of these two elements. This value would then be divided by the national average. This calculation would result in a hospital-specific value, which reflects wage levels in the areas from which a hospital hires, accounting for variation in the proportion of workers hired from each area.

Using more precisely defined labor markets, the CBWI values can vary for hospitals within the same CBSA or county and, thus, more precisely reflect wage differences within and across CBSA boundaries and address intra-area variation more precisely than the current system. Although the CBWI would allow wage index values to vary within a CBSA, the CBWI is less likely to produce large differences—or ''cliffs''—between wage index values for nearby hospitals in adjacent CBSAs because nearby hospitals likely hire workers from areas in similar proportions.

Acumen found in its analysis that the CBWI system would more closely reflect hospitals' actual wages than the current CBSA-based system. Acumen suggested the CBWI has the potential to reduce the need for exceptions and adjustments and further manipulation of wage index values to prevent these ''cliffs'' between labor market areas.

The April 12, 2012 Report to Congress detailed several findings relevant to implementation of a CBWI:

- Because the CBWI accounts for specific differences in hospitals' geographic hiring patterns, it would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on BLS data for health care industry workers.
- While a CBWI could be constructed with the most recent Census commuting data, were the CBWI to be adopted, a more up-to-date reporting system for collecting commuting data from hospitals would potentially have to be established so that the wage index calculations would accurately reflect the commuting patterns of hospital employees.
- Concerns about a CBWI leading to hospitals altering hiring patterns and distorting labor markets do not appear to be worse than under the current system and could potentially be mitigated with policy adjustments.
- As current statutory provisions governing the Medicare wage index and exceptions to that wage index were designed for the current MSA-based wage index system, their applicability would need to be reviewed if a CBWI were to be adopted.
- The Medicare statute has traditionally applied payment changes in a budget neutral manner. If a CBWI were to be adopted in a budget neutral manner, payments to some providers would increase while payments to other providers would decrease.

The complete report can be accessed on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html.*

We received many public comments regarding the April 2012 Report to Congress as part of the FY 2013 IPPS rulemaking (77 FR 53660 through 53663). Again, the public comments varied greatly, and there was no consensus position among the commenters. The complete set of the public comments on the FY 2013 IPPS/LTCH PPS proposed rule (CMS–1588–P) is available via the Internet on the website at: *www.regulations.gov.*

d. Institute of Medicine (IOM) Study on Medicare's Approach to Measuring Geographic Variations in Hospitals' Wage Costs

In addition to submitting the 2012 Report to Congress, in April 2012, the Secretary commissioned the Institute of Medicine (IOM) to evaluate Medicare's approach for measuring geographic variation in the wage costs faced by hospitals. In the report, IOM's Committee on Geographic Adjustment Factors in Medicare Payment proposed a set of recommendations for modifying the hospital wage index in both the method used in its construction and the data used in its calculation.

In constructing the wage index, the IOM recommended altering the current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live. The IOM's recommendation is based on its theory that county-to-MSA commuting patterns reveal the degree of integration of labor markets across geographically drawn boundaries (that is, MSAs) and a commuting-based smoothing adjustment to the wage index would more accurately measure the market wage each hospital faces. The IOM model used workers' out-commuting patterns to smooth wage index values for hospitals in different counties, similar to the out-migration adjustment used in the current wage index system. The IOM also suggested that using out-commuting shares in the smoothing adjustment creates an index based on the wage levels of workers living in that area in which a hospital is located, as opposed to wage levels of workers employed in that area, as in the CBWI model. In calculating its smoothed wage index, the IOM uses the following four steps:

- Step 1—Compute a wage index for each MSA, adhering to Medicare's current approach for calculating the average hourly wage (AHW) paid by all IPPS hospitals located in the MSA (this step replicates the current pre-reclassification wage index).
- Step 2—Compute an area wage for each county equal to a weighted average of MSA-level AHWs, where the weight for each MSA measures the share of all hospital workers living in the county who commute to hospitals located in that MSA.
- Step 3—Assign all hospitals located in the county a hospital wage index value equal to the county area wage index.
- Step 4—Normalize wage indexes to ensure budget neutrality, similar to the approach currently implemented by Medicare.

In addition, the IOM's wage index model uses hourly wage data from the BLS Occupational Employment Survey rather than from hospital cost reports. The IOM also recommended measuring hourly wages using data for all health care workers, rather than only hospital workers, and using a fuller set of occupations incorporated in the hospital wage index occupational mix adjustment. The IOM suggested that BLS data would reduce administrative burdens placed upon hospitals and, by broadening the array of reported occupations from what is currently covered in the hospital cost report, would achieve more accurate labor market definitions and reduce year-to-year volatility. The IOM encouraged CMS to establish an ongoing agreement with the BLS to use occupational survey data specific to health care workers to calculate average hourly wage values. The IOM suggested, for instance, that the 5-year American Community Survey is a potential source of the necessary commuting information.

The findings indicated that the IOM hospital wage index method would result in the reduction in wage index ''cliffs,'' and would diminish the need to maintain current wage index exceptions and adjustments. The IOM also recommended that the hospital wage values should be applied to other nonhospital health care providers, shifting to a single measurement of geographic variation to be used in multiple Medicare provider payment systems.

The IOM's Phase I report, published in September 2011, is available via the Internet on the website at: *http://nationalacademies.org/hmd/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.*

We received many public comments regarding the IOM Report as part of the FY 2013 IPPS rulemaking (77 FR 53660 through 53663). Again, the public comments varied greatly, and there was no consensus position among the commenters. The complete set of the public comments on the FY 2013 IPPS/LTCH PPS proposed rule (CMS–1588–P) is available via the Internet on the website at: *www.regulations.gov.*

As stated earlier, given that some time has elapsed since the MedPAC, Acumen, CMS, and the IOM examined disparities between the wage index values for individual hospitals and the wage index values among different geographic areas, and ways to improve the Medicare wage index, in this proposed rule, we are taking this opportunity to invite the public to submit further comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index. For example, some stakeholders in recent years have expressed the belief that the existing wage index disparities between high and low wage index areas are too great, particularly for rural hospitals and/or financially struggling hospitals. They have suggested additional floors be created for low wage index areas, or that the portion of the IPPS payment adjusted by the wage index be lowered from the current statutory 62 percent for hospitals with a wage index value below 1.0 to a smaller percentage. Some stakeholders also have stated that the reporting lag from when hospitals raise wages and when those increased wages become reflected in the Medicare wage index is a barrier to addressing wage index disparities. Other stakeholders have echoed previous recommendations that the Medicare wage index should be based on a different source of data, such as data from the Bureau of Labor Statistics.

If practicable, we are requesting commenters to submit supporting data and specific recommendations in their comments. For any suggestions or recommendations that would involve novel legal questions, we welcome analysis regarding CMS' authority for our consideration.

IV. Other Decisions and Proposed 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)).

2. Proposed Changes for FY 2019

As discussed in section II.F. of the preamble of this proposed rule, based on our analysis of FY 2017 MedPAR claims data, we are proposing to make changes to a number of MS–DRGs, effective for FY 2019. Specifically, we are proposing to:

- Assign CAR–T therapy procedure codes to MS–DRG 016 (proposed revised title: Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy);
- Delete MS–DRG 685 (Admit for Renal Dialysis) and reassign diagnosis codes from MS–DRG 685 to MS–DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively);
- Delete 10 MS–DRGs (MS–DRGs 765, 766, 767, 774, 775, 777, 778, 780, 781, and 782) and create 18 new MS–DRGs relating to Pregnancy, Childbirth and the Puerperium (MS–DRGs 783 through 788, 794, 796, 798, 805, 806, 807, 817, 818, 819, and 831 through 833);
- Assign two additional diagnosis codes to 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);
- Reassign 12 ICD–10–PCS procedure codes from MS–DRGs 329, 330 and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 344, 345, and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively); and
- Reassign ICD–10–CM diagnosis codes R65.10 and R65.11 from MS–DRGs 870, 871, and 872 (Septicemia or Severe Sepsis with and without Mechanical Ventilation 96 Hours with and without MCC, respectively) to MS–DRG 864 (proposed revised title: Fever and Inflammatory Conditions).

In light of the proposed changes to these MS–DRGs for FY 2019, according to the regulations under § 412.4(d), we have evaluated these MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2017 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 reassess MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. MS–DRGs 023, 329, 330, 331, 698, 699, 700, 870, 871, and 872 are currently subject to the postacute care transfer policy. As a result of our review, these MS–DRGs, 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.

Using the March 2018 update of the FY 2017 MedPAR file, we have developed the following chart which sets forth the most recent 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. We note that this analysis does not take into account the proposed change relating to discharges to hospice care, effective October 1, 2018, discussed in section IV.A.3. of the preamble of this proposed rule. For the FY 2019 final rule, we will update this analysis using the most recent available data at that time.

LIST OF PROPOSED NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2019

Proposed new or revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,372)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.977208%)	Postacute care transfer policy status
016	Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy (Proposed Revised).	2,064	*417	126	6.10	No.

LIST OF PROPOSED NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2019—Continued

Proposed new or revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,372)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.977208%)	Postacute care transfer policy status
023	Craniotomy with Major Device Implant or Acute CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator (Proposed Revised).	9,436	4,990	1,264	13.40	Yes.
329	Major Small and Large Bowel Procedures with MCC (Proposed Revised).	35,361	21,816	7,058	19.96	Yes.
330	Major Small and Large Bowel Procedures with CC (Proposed Revised).	52,702	23,575	6,178	11.72	Yes.
331	Major Small and Large Bowel Procedures without CC/MCC (Proposed Revised).	2,9685	6,713	543	*1.83	Yes.**
344	Minor Small and Large Bowel Procedures with MCC (Proposed Revised).	1,285	*675	206	16.03	No.
345	Minor Small and Large Bowel Procedures with CC (Proposed Revised).	2,475	*989	202	8.16	No.
346	Minor Small and Large Bowel Procedures without CC/MCC (Proposed Revised).	1,274	*328	71	*5.58	No.
698	Other Kidney and Urinary Tract Diagnoses with MCC (Proposed Revised).	5,6925	34,672	8,351	14.67	Yes.
699	Other Kidney and Urinary Tract Diagnoses with CC (Proposed Revised).	33,945	15,263	3,132	9.23	Yes.
700	Other Kidney and Urinary Tract Diagnoses without CC/MCC (Proposed Revised).	4,431	1,589	181	*4.08	Yes.**
783	Cesarean Section with Sterilization with MCC (Proposed New).	191	*6	0	*0	No.
784	Cesarean Section with Sterilization with CC (Proposed New).	548	*19	0	*0	No.
785	Cesarean Section with Sterilization without CC/MCC (Proposed New).	502	*6	0	*0	No.
786	Cesarean Section without Sterilization with MCC (Proposed New).	739	*34	5	**0.7	No.
787	Cesarean Section without Sterilization with CC (Proposed New).	2,034	*93	3	*0.15	No.
788	Cesarean Section without Sterilization without CC/MCC (Proposed New).	1,854	*41	0	*0	No.
794	Vaginal Delivery with Sterilization/D&C with MCC (Proposed New).	1	*1	0	*0	No.
796	Vaginal Delivery with Sterilization/D&C with CC (Proposed New).	49	*2	0	*0	No.
798	Vaginal Delivery with Sterilization/D&C without CC/MCC (Proposed New).	162	*1	0	*0	No.
805	Vaginal Delivery without Sterilization/D&C with MCC Proposed New).	506	*20	0	*0	No.
806	Vaginal Delivery without Sterilization/D&C with CC (Proposed New).	2,128	*72	2	*0	No.
807	Vaginal Delivery without Sterilization/D&C without CC/MCC (Proposed New).	3,809	*69	6	*0	No.
817	Other Antepartum Diagnoses with O.R. Procedure with MCC (Proposed New).	76	*12	0	*0	No.
818	Other Antepartum Diagnoses with O.R. Procedure with CC (Proposed New).	85	*5	1	*1.18	No.
819	Other Antepartum Diagnoses with O.R. Procedure without CC/MCC (Proposed New).	49	*0	0	*0	No.
831	Other Antepartum Diagnoses without O.R. Procedure with MCC (Proposed New).	857	*30	1	*0.12	No.
832	Other Antepartum Diagnoses without O.R. Procedure with CC (Proposed New).	1,241	*52	13	*1.05	No.
833	Other Antepartum Diagnoses without O.R. Procedure without CC/MCC (Proposed New).	659	*11	0	*0	No.

LIST OF PROPOSED NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2019—Continued

Proposed new or revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,372)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.977208%)	Postacute care transfer policy status
864	Fever and Inflammatory Conditions (Proposed Revised).	12,150	3,882	286	*2.35	No.
870	Septicemia or Severe Sepsis with Mechanical Ventilation 96 Hours (Proposed Revised).	34,335	15,099	4,988	14.53	Yes.
871	Septicemia or Severe Sepsis without Mechanical Ventilation 96 Hours with MCC (Proposed Revised).	592,110	281,401	43,504	*7.35	Yes.**
872	Septicemia or Severe Sepsis without Mechanical Ventilation 96 Hours without MCC (Proposed Revised).	154,469	64,490	6,848	*4.43	Yes.**

* 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 March 2018 update of the FY 2017 MedPAR file, we have identified MS–DRGs that we are proposing to be included on the list of MS–DRGs subject to the special payment methodology policy. None of the proposed revised MS–DRGs that are listed in the table above as continuing to meet the criteria for postacute care transfer policy status (specifically, MS–DRGs 023, 330, 331, 698, 699, 700, 870, 871, and 872) are currently listed as being subject to the special payment methodology. Based on our analysis of proposed changes to MS–DRGs included in this proposed rule, we have determined that proposed revised MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) would meet the criteria for the MS–DRG special payment methodology. Therefore, we are proposing that proposed revised MS–DRG 023 would be subject to the MS–DRG special payment methodology, effective FY 2019. As described in the regulations at § 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. Therefore, we are proposing that MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) also would be subject to the MS–DRG special payment methodology, effective for FY 2019.

LIST OF PROPOSED REVISED MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2019

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	Special payment policy status
023	Craniotomy with Major Device Implant or Acute CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator.	7.3	$138,521	$96,268	Yes.
330	Major Small and Large Bowel Procedures with CC	6.1	32,410	41,813	No.
331	Major Small and Large Bowel procedures without CC/MCC	3.7	34,430	28,931	No.
698	Other Kidney and Urinary Tract Diagnoses with MCC	4.9	17,966	24,920	No.
699	Other Kidney and Urinary Tract Diagnoses with CC	3.4	17,040	17,012	No.
700	Other Kidney and Urinary Tract Diagnoses without CC/MCC	2.5	14,592	12,954	No.
870	Septicemia or Severe Sepsis with Mechanical Ventilation <96 Hours.	12.4	0	102,333	No.
871	Septicemia or Severe Sepsis without Mechanical Ventilation <96 Hours with MCC.	4.8	19,479	29,746	No.
872	Septicemia or Severe Sepsis without Mechanical Ventilation <96 Hours without MCC.	3.6	18,911	17,193	No.

We are inviting public comments on this proposal.

The proposed 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.

3. Proposed Implementation of Changes Required by Section 53109 of the Bipartisan Budget Act of 2018

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 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 would be subject to payment as a transfer case. We are proposing to make 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 are proposing 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) would be 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 will be 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.

We are inviting public comments on our proposals.

B. Proposed Changes in the Inpatient Hospital Update for FY 2019 (§ 412.64(d))

1. Proposed FY 2019 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 2019, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2018. 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 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) 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;

(b) 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;

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and

(d) An additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act.

Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2019 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

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 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 2019 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2017 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2017, which is estimated to be 2.8 percent. We 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 2019 market basket update and the MFP adjustment in the final rule.

For FY 2019, 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.* As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our website rather than in the annual rulemaking.

For FY 2019, we are proposing an MFP adjustment of 0.8 percentage point. Similar to the market basket update, for this proposed rule, we used IGI's fourth quarter 2017 forecast of the MFP adjustment to compute the proposed 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 2019 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 2019, as specified in the following table:

PROPOSED FY 2019 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2019	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	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.1	0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.25	−0.85	0.55	−1.55

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2019 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to revise paragraph (vii) of § 412.64(d)(1) to include the applicable percentage increase to the FY 2019 operating standardized amount 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 and less an additional reduction of 0.75 percentage point.

We are inviting public comments on our proposals.

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. (As discussed in section IV.G. of the preamble of this FY 2019 IPPS/LTCH PPS proposed rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted on April 16, 2015) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.)

For FY 2019, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 1.25 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.55 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of -0.85 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of −1.55 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As noted previously, for this FY 2019 IPPS/LTCH PPS proposed rule, we are using IGI's fourth quarter 2017 forecast of the 2014-based IPPS market basket update with historical data through third quarter 2017. Similarly, we are using IGI's fourth quarter 2017 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.

We are inviting public comments on our proposal.

2. Proposed FY 2019 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 2019 IPPS/LTCH PPS proposed rule, for FY 2019, we are proposing an applicable percentage increase of 1.25 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 2019.

We are inviting public comments on our proposals.

C. 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 some 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 (c)(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 2019 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2019 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 2017 (October 1, 2016 through September 30, 2017), and include bills posted to CMS' records through December 2017.

In this FY 2019 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, 2018, they must have a CMI value for FY 2017 that is at least—

- 1.66185 (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 the table below. We intend to update these proposed CMI values in the FY 2019 final rule to reflect the updated FY 2017 MedPAR file, which will contain data from additional bills received through March 2018.

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.4071
2. Middle Atlantic (PA, NJ, NY)	1.4694
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5486
4. East North Central (IL, IN, MI, OH, WI)	1.5765
5. East South Central (AL, KY, MS, TN)	1.5289
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.6387
7. West South Central (AR, LA, OK, TX)	1.6872
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7366
9. Pacific (AK, CA, HI, OR, WA)	1.6619

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.

We are inviting public comments on our proposal.

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. In this FY 2019 IPPS/LTCH PPS proposed rule, for FY 2019, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2016 (that is, October 1, 2015 through September 30, 2016), 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, 2018, must have, as the number of discharges for its cost reporting period that began during FY 2016, 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, as reflected in the table below. We intend to update these numbers in the FY 2019 final rule based on the latest available cost report data.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,431
2. Middle Atlantic (PA, NJ, NY)	9,762
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,643
4. East North Central (IL, IN, MI, OH, WI)	8,297
5. East South Central (AL, KY, MS, TN)	7,796
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,721
7. West South Central (AR, LA, OK, TX)	5,456
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,819
9. Pacific (AK, CA, HI, OR, WA)	9,017

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.

We are inviting public comments on our proposal.

D. 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.

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, as discussed later in this section.). 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. (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 appears elsewhere in this issue of the **Federal Register**.) In section IV.D.2.b. of the preamble of this proposed rule, we discuss the proposed low-volume hospital payment adjustment policies for FY 2019.

2. Proposed Implementation of Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology Made by the Bipartisan Budget Act of 2018

a. Extension of the Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FY 2018 and Proposed Conforming Changes to Regulations

Section 50204 of the Bipartisan Budget Act of 2018 extended through FY 2018 certain changes to the low-volume hospital payment policy made by the Affordable Care Act and extended by subsequent legislation. We addressed this extension of the temporary changes to the low-volume hospital payment policy for FY 2018 in a notice (CMS–1677–N) that appears elsewhere in this issue of the **Federal Register**. However, in this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to make conforming changes to the regulations text in § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2018, in accordance with section 50204 of the Bipartisan Budget Act of 2018. Specifically, we are proposing to make conforming changes to paragraphs (b)(2)(ii) and (c)(2) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect for FY 2018 is the same

low-volume hospital payment adjustment policy in effect for FYs 2011 through 2017 (as described in the FY 2018 IPPS notice (CMS–1677–N) that appears elsewhere in this issue of the **Federal Register**).

b. 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, section 50204 amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act 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 50204 also amended section 1886(d)(12)(D) of the Act 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).

To implement this requirement, we are proposing 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 are proposing that qualifying hospitals with 500 or fewer total discharges would 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 would be calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. That proportion is calculated by multiplying the discharges in excess of 500 by a fraction that is equal to the maximum available add-on payment (25 percent) divided by a number represented by the range of discharges for which this policy applies (3,800 minus 500, or 3,300). In other words, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, we are proposing the low-volume hospital payment adjustment for FYs 2019 through 2022 would be calculated using the following formula:

$$\text{Low-Volume Hospital Payment Adjustment} = 0.25 - [0.25/3300] \times (\text{number of total discharges} - 500) = (95/330) \times (\text{number of total discharges}/13{,}200).$$

To reflect these changes for FYs 2019 through 2022, we are proposing to revise § 412.101(b)(2) by adding paragraph (iii) to specify that a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 15 road miles from the nearest ''subsection (d)'' hospital, consistent with the amendments to section 1886(d)(12)(C)(i) of the Act as provided by section 50204(a)(2) of the Bipartisan Budget Act of 2018. We also are proposing to add paragraph (3) to § 412.101(c), consistent with section 1886(d)(12)(D) of the Act as amended by section 50204(a)(3) of the Bipartisan Budget Act of 2018, to specify that:

- For low-volume hospitals with 500 or fewer total discharges during the fiscal year, the low-volume hospital payment adjustment is an additional 25 percent for each Medicare discharge.
- For low-volume hospitals with total discharges during the fiscal year of more than 500 and fewer than 3,800, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(95/330) × (number of total discharges/13,200)].

The ''number of total discharges'' would be 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.

In addition, in accordance with the provisions of section 50204(a) of the Bipartisan Budget Act of 2018, for FY 2023 and subsequent fiscal years, we are proposing to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that the low-volume payment adjustment policy in effect for these years is the same low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described earlier. Lastly, we are proposing to make conforming changes to paragraph (d) (which relates to eligibility of new hospitals for the adjustment), consistent with the provisions of section 50204(a) of the Bipartisan Budget Act of 2018, for FY 2019 and subsequent fiscal years, as total discharges are used under the low-volume hospital payment adjustment policy in effect for those years as described earlier.

3. Proposed 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 2018 IPPS/LTCH PPS final rule (82 FR 38186 through 38188)), 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, 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 2018 IPPS/LTCH PPS final rule (82 FR 38185 through 38188).)

As described 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 proposed new § 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. 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.

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 proposed new § 412.101(b)(2)(iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2019, as noted earlier, 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.

Specifically, for FY 2019, 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 2019, we are proposing that a hospital's written request must be received by its MAC no later than September 1, 2018 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2018. If a hospital's written request for low-volume hospital status for FY 2019 is received after September 1, 2018, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2019 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2018 may continue to receive a low-volume hospital payment adjustment without reapplying if it continues to meet the mileage criterion (which remains unchanged for FY 2019) and it also meets the applicable discharge criterion as modified for FY 2019 (that is, 3,800 or fewer total discharges). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2019. (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).

We are inviting public comments on our proposal.

E. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

1. IME Payment Adjustment Factor for FY 2019

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 2019, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2019 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.

2. Proposed Technical Correction to Regulations at 42 CFR 412.105(f)(1)(vii)

In the regulation governing the IME payment adjustment at § 412.105(f)(1)(vii), we have identified an inadvertent omission of a cross-reference relating to an adjustment to a hospital's full-time equivalent cap for a new medical residency training program. Section 412.105(f)(1)(vii) states that if a hospital establishes a new medical residency training program, as defined in § 413.79(l), the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of § 413.79(e)(1) through (e)(4). However, there is a paragraph (e)(5) under § 413.79 that we have inadvertently omitted that applies to the regulation at § 412.105(f)(1)(vii). In this proposed rule, we are proposing to correct this omission by removing the reference to ''§ 413.79(e)(1) through (e)(4)'' and adding in its place the reference ''§ 413.79(e)'' to make clear that the provisions of § 413.79(e)(1) through (e)(5) apply. This proposed revision is intended to correct the omission and is not intended to substantially change the underlying regulation.

F. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2019 (§ 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 the FY 2015 IPPS/LTCH PPS final rule (79 FR 50006), we specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. We refer readers to those two final rules for a detailed discussion of our policies. In summary, we specified the following:

- *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 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals would be paid under the Maryland All-Payer Model. The Maryland All-Payer Model was scheduled to end on December 31, 2018, but CMS and the State have agreed to extend it through December 31, 2019. Alternatively, CMS and the State may enter into an agreement to govern payments to Maryland hospitals under a new payment model. Under either scenario, Maryland hospitals would not be paid under the IPPS in FY 2019, and would remain ineligible to receive empirically justified Medicare DSH payments or 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 numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based 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. As a result, there are currently 30 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, these hospitals do not receive empirically justified Medicare DSH payments, and they are 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. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2018, and our proposed policies for FY 2019.

a. Calculation of Proposed Factor 1 for FY 2019

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 2018, in this FY 2019 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2019, 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. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2019.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2019 (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 report with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File.

For purposes of calculating the proposed Factor 1 and modeling the impact of this FY 2019 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's December 2017 Medicare DSH estimates, which were based on data from the December 2017 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2018 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2018 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 2017 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 2017 Medicare DSH estimates. The 30 hospitals 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 discussed above, the Office of the Actuary used the most recently submitted Medicare cost report data for FY 2015 to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2018 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The December 2017 Office of the Actuary estimate for Medicare DSH payments for FY 2019, without regard to the application of section 1886(r)(1) of the Act, was approximately $16.295 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on the December 2017 estimate, the estimate of empirically justified Medicare DSH payments for FY 2019, with the application of section 1886(r)(1) of the Act, is approximately $4.074 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2019). 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 2019 will be $12,221,027,954.62, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2018 ($16,294,703,939.49 minus $4,073,675,984.87).

The Office of the Actuary's estimates for FY 2019 for this proposed rule began with a baseline of $13.232 billion in Medicare DSH expenditures for FY 2015. The following table shows the factors applied to update this baseline through the current estimate for FY 2019:

FACTORS APPLIED FOR FY 2016 THROUGH FY 2019 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2015 BASELINE

FY	Update	Discharges	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2016	1.009	0.9864	1.031	1.046	1.073333	14.202
2017	1.0015	0.9925	1.004	1.0657	1.063531	15.105
2018	1.018088	0.9921	1.005	1.02745	1.04296	15.754
2019	1.0175	1.011	1.005	1.0005	1.034353	16.295

* Rounded.

In this table, the discharges column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figure for FY 2016 is based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2017 is based on preliminary data for 2017. The discharge figures for FYs 2018 and 2019 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 2016 and FY 2017 are based on actual data adjusted by a completion factor. The FY 2018 increase is based on preliminary data. The FY 2018 and FY 2019 increases are estimates and are 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 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in States that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 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 2016 Actuarial Report on the Financial Outlook for Medicaid (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2016.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.

The table below shows the factors that are included in the ''Update'' column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2016	2.4	−0.2	−0.5	−0.8	0.9
2017	2.7	−0.75	−0.3	−1.5	0.15
2018	2.7	−0.75	−0.6	0.4588	1.8088
2019	2.8	−0.75	−0.8	0.5	1.75

Note: All numbers are based on the FY 2019 President's Budget projections.

We are inviting public comments on our proposed methodology for calculation of Factor 1 for FY 2019.

b. Calculation of Proposed Factor 2 for FY 2019

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that, for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (1) who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 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. Specifically, the statute states 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.

(2) Proposed Methodology for Calculation of Factor 2 for FY 2019

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 to determine Factor 2 for FY 2019.

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 mix is integral to the well-established NHEA methodology. Below 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 and that we believe continue to be relevant in developing the estimate for FY 2019. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.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 2016, 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 2016. 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 2014, OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS). For both 2015 and 2016, OACT's estimates of the rate of uninsurance are derived by applying the NHIS data on the proportion of uninsured individuals to the total U.S. population as described above. 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 calendar years 2018 and 2019. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2017 through 2026) use the latest NHEA historical data, which presently run through 2016. 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.*

As discussed in the FY 2018 IPPS/LTCH PPS final rule, 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.

Using these data sources and the methodologies described above, OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2018 and 2019 is 9.1 percent and 9.6 percent, respectively. 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 in each fiscal year since FY 2014.

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 2019. 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.

The calculation of the proposed Factor 2 for FY 2019 using a weighted average of OACT's projections for CY 2018 and CY 2019 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2018: 9.1 percent.
- Percent of individuals without insurance for CY 2019: 9.6 percent.
- Percent of individuals without insurance for FY 2019 (0.25 times 0.091) + (0.75 times 0.096): 9.48 percent.

$1 - |((0.0948 - 0.14)/0.14)| = 1 - 0.3229 =$ 0.6771 (67.71 percent)

0.6771 (67.71 percent) − .002 (0.2 percentage points for FY 2019 under section 1886(r)(2)(B)(ii) of the Act) = 0.6751 or 67.51 percent

0.6751 = Factor 2

Therefore, the proposed Factor 2 for FY 2019 is 67.51 percent.

The proposed FY 2019 uncompensated care amount is: $\$12,221,027,954.62 \times 0.6751 = \$8,250,415,972.16$.

Proposed FY 2019 Uncompensated Care Amount	$8,250,415,972.16

We are inviting public comments on our proposed methodology for calculation of Factor 2 for FY 2019.

c. Calculation of Proposed Factor 3 for FY 2019

(1) 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 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 can 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. The most recent update of this analysis, which used IRS Form 990 data for tax years 2011, 2012, and 2013 (the latest available years) as a benchmark, found that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data continue to be highly correlated and that this correlation continues to increase over time, from 0.80 in 2011 to 0.85 in 2013.

This empirical evidence 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 in 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.

In summary, as we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38203), when weighing the new information regarding the growing correlation between the Worksheet S–10 data and IRS 990 data that became available to us after the FY 2017 rulemaking in conjunction with the information regarding Worksheet S–10 data and the low-income days proxy that we had analyzed as part of our consideration of this issue in prior rulemaking, we determined 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. We also stated that we believe that continued use of Worksheet S–10 will improve the accuracy and consistency of the reported data, especially in light of CMS' concerted efforts to allow hospitals to review and resubmit their Worksheet S–10 data for past years and the use of select audit protocols to trim aberrant data and replace them with more reasonable amounts. We also committed to continue to work with stakeholders to address their concerns regarding the accuracy of the reporting of uncompensated care costs through provider education and refinement of the instructions to Worksheet S–10.

(2) Methodology Used To Calculate Factor 3 in Prior Fiscal Years

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 2017 IPPS/LTCH PPS final rule, in order to mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods, we finalized a policy of calculating a hospital's share of uncompensated care based on an average of data derived from three cost reporting periods instead of one cost reporting period. As explained in the preamble to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959), instead of determining Factor 3 using data from a single cost reporting period as we did in FY 2014, FY 2015, and FY 2016, we used data from three cost reporting periods (Medicaid data for FYs 2011, 2012, and 2013 and SSI days from the three most recent available years of SSI utilization data (FYs 2012, 2013, and 2014)) to compute Factor 3 for FY 2017. Furthermore, instead of determining a single Factor 3 as we had done since the first year of the uncompensated care payment in FY 2014, we calculated an individual Factor 3 for each of the three cost reporting periods, which we then averaged by the number of cost reporting years with data to compute the final Factor 3 for a hospital. Under this policy, if a hospital had merged, we would combine data from both hospitals for the cost reporting periods in which the merger was not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we combined data from the multiple cost reports so that a hospital could have a Factor 3 calculated using more than one cost report within a cost reporting period. We codified these changes for FY 2017 by amending the regulations at § 412.106(g)(1)(iii)(C).

For FY 2018, consistent with the methodology used to calculate Factor 3 for FY 2017, we advanced the time period of the data used in the calculation of Factor 3 forward by one year and used data from FY 2012, FY 2013, and FY 2014 cost reports. We believed it would not be appropriate to use Worksheet S–10 data for periods prior to FY 2014, as hospitals did not have notice that the Worksheet S–10 data from these years might be used for purposes of computing uncompensated care payments and, as a result, may not have fully appreciated the importance of reporting their uncompensated care costs as completely and accurately as possible. Rather, for cost reporting periods prior to FY 2014, we believed it would be appropriate to continue to use low-income insured days. Accordingly, for the time period consisting of three cost reporting years, including FY 2014, FY 2013, and FY 2012, we used Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured days proxy data for the two earlier cost reporting periods. In order to perform this calculation, we drew three sets of data (2 years of Medicaid utilization data and 1 year of Worksheet S–10 data) from the most recent available HCRIS extract. Accordingly, for FY 2018, in addition to the Worksheet S–10 data for FY 2014, we used Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We also continued to use FY 2012 cost report data submitted to CMS by IHS and Tribal hospitals to determine FY 2012 Medicaid days for those hospitals. (Cost report data from IHS and Tribal hospitals are included in HCRIS beginning in FY 2013 and are no longer submitted separately.) We continued the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers as well as the policies finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957).

To limit the effect of aberrant reporting of Worksheet S–10 data, we identified those hospitals that had high levels of reported uncompensated care relative to the total operating costs reported on the cost report. Specifically, for those hospitals where the ratio of uncompensated care costs relative to total operating costs for the hospital's 2014 cost report exceeded 50 percent, we determined the ratio of uncompensated care costs relative to total operating costs from the hospital's 2015 cost report and applied that ratio to the hospital's total operating costs from the 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We then substituted this amount for the FY 2014 Worksheet S–10 data when determining Factor 3 for FY 2018. We believed that this approach, which affected the data for three hospitals in FY 2018, balanced our desire to exclude potentially aberrant data from a small number of hospitals in the determination of Factor 3 with our concern regarding inappropriately reducing FY 2018 uncompensated care payments to a hospital that may have a legitimately high ratio. We stated our intent to consider in future rulemaking whether continued use of this adjustment or an

alternative adjustment is necessary for subsequent years.

Due to concerns that the uncompensated care data reported by Puerto Rico hospitals and Indian Health Service and Tribal hospitals need to be examined further, we concluded that the Worksheet S–10 data for these hospitals should not be used to determine Factor 3 for FY 2018 (82 FR 38209). We also determined that Worksheet S–10 data should not be used to determine Factor 3 for All-Inclusive Rate Providers, whose CCRs were deemed to be potentially erroneous and in need of further examination (82 FR 38212). For the reasons described earlier related to the impact of the Medicaid expansion beginning in FY 2014, we did not believe it was appropriate to calculate a Factor 3 for these hospitals using FY 2014 low-income insured days. Because we did not believe it was appropriate to use the FY 2014 uncompensated care data for these hospitals and we also did not believe it was appropriate to use the FY 2014 low-income insured days, we concluded that the best proxy for the costs of Puerto Rico, Indian Health Service and Tribal hospitals, and All-Inclusive Rate Providers for treating the uninsured is the low-income insured days data for FY 2012 and FY 2013. Accordingly, in order to determine the Factor 3 for FY 2018 for these hospitals, we calculated an average of three individual Factor 3s using the Factor 3 calculated using FY 2013 cost report data twice and the Factor 3 calculated using FY 2012 cost report data once. We believed it was appropriate to double-weight the Factor 3 calculated using FY 2013 data as it reflects the most recent available information regarding the hospital's low-income insured days before any expansion of Medicaid. We stated that we would reexamine the use of the Worksheet S–10 data for Puerto Rico, Indian Health Service and Tribal hospitals, and All-Inclusive Rate Providers as part of the FY 2019 rulemaking. In addition, for Puerto Rico hospitals, we continued to use a proxy for SSI days consisting of 14 percent of a hospital's Medicaid days, as was first applied in FY 2017 (82 FR 38209).

Therefore, for FY 2018, we computed a Factor 3 for each hospital by—

- Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- Step 2: Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- Step 3: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data (or using the Factor 3 calculated in Step 2 for Puerto Rico, IHS/Tribal hospitals, and All-Inclusive Rate Providers); and
- Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

We stated our belief that if we were to propose to continue this methodology for FY 2019 and FY 2020, this approach would have the effect of transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 because an additional year of Worksheet S–10 data would be incorporated into the calculation of Factor 3 in FY 2019, and the use of low-income insured days would be phased out by FY 2020.

(3) Proposed Methodology for Calculating Factor 3 for FY 2019

Since the publication of the FY 2018 IPPS/LTCH PPS final rule, we have continued to monitor the reporting of Worksheet S–10 data in anticipation of using Worksheet S–10 data from hospitals' FY 2014 and FY 2015 cost reports in the calculation of Factor 3. We acknowledge the concerns that have been raised regarding the instructions for Worksheet S–10. In particular, commenters have expressed concerns that the lack of clear and concise line level instructions prevents accurate and consistent data from being reported on Worksheet S–10. We note that, in November 2016, CMS issued Transmittal 10, which clarified and revised the instructions for the Worksheet S–10, including the instructions regarding the reporting of charity care charges. Transmittal 10 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R10P240.pdf.* In Transmittal 10, we clarified that hospitals may include discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period. This clarification applied to cost reporting periods beginning prior to October 1, 2016, as well as cost reporting periods beginning on or after October 1, 2016. As a result, nothing prohibits a hospital from considering a patient's insurance status as a criterion in its charity care policy. A hospital determines its own financial criteria as part of its charity care policy. The instructions for the Worksheet S–10 set forth that hospitals may include discounts given to uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider, who meet the hospital's charity care criteria in effect for that cost reporting period. In addition, we revised the instructions for the Worksheet S–10 for cost reporting periods beginning on or after October 1, 2016, to provide that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service.

During the FY 2018 rulemaking, commenters pointed out that, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56963), CMS agreed to institute certain additional quality control and data improvement measures prior to moving forward with incorporating Worksheet S–10 data into the calculation of Factor 3. However, the commenters indicated that, aside from a brief window in 2016 for hospitals to submit corrected data on their FY 2014 Worksheet S–10 by September 30, 2016, and the issuance of revised instructions (Transmittal 10) in November 2016 that are applicable to cost reports beginning on or after October 1, 2016, CMS has not implemented any additional quality control and data improvement measures. We stated in the FY 2018 IPPS/LTCH PPS final rule that we would continue to work with our stakeholders to address their concerns regarding the reporting of uncompensated care through provider education and refinement of the instructions to the Worksheet S–10 (82 FR 38206).

On September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, nonreimbursed Medicare bad debt, and charity care, as well as modified the calculations relative to uncompensated care costs and added 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 apply 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 nonreimbursed 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.

We also provided another opportunity for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports. We refer readers to Change Request 10378, Transmittal 1981, titled ''Fiscal Year (FY) 2014 and 2015 Worksheet S–10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals,'' issued on December 1, 2017 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1981OTN.pdf*). In this transmittal, we instructed MACs to accept amended Worksheets S–10 for FY 2014 and FY 2015 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none have been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal states that hospitals must submit their amended FY 2014 and FY 2015 cost reports 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 January 2, 2018. We note that this transmittal supersedes the previous deadline in Change Request 10026, which was issued on June 30, 2017, with respect to the dates by which hospitals must submit their revised or newly submitted Worksheet S–10 in order to be considered for purposes of this rulemaking, as well as the dates by which MACs must accept these data and upload a revised cost report to HCRIS. Under the deadlines established in Change Request 10378, in order for revisions to be guaranteed consideration for this FY 2019 proposed rule, hospitals had to submit their amended FY 2014 and FY 2015 cost reports 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 December 1, 2017. We also indicated that, all revised data received by December 1, 2017, would be considered for purposes of this FY 2019 IPPS/LTCH PPS proposed rule, and all revised data received by the January 2, 2018 deadline would be available to be considered for purposes of the FY 2019 IPPS/LTCH PPS final rule.

However, for this FY 2019 IPPS/LTCH PPS proposed rule, we were able to include data updated in HCRIS through February 15, 2018. Specifically, in light of the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline for resubmitting Worksheets S–10 for FY 2014 and FY 2015 through January 2, 2018, we believed it was appropriate to use data updated through February 15, 2018, rather than the December 2017 HCRIS update, which we typically use for the annual proposed rule. We believe that providing the additional time to allow cost reports that may have been delayed due to these unique circumstances to be included in our calculations for purposes of this FY 2019 proposed rule, enabled us to use more accurate uncompensated care cost data in calculating the proposed Factor 3 values.

We examined hospitals' FY 2014 and FY 2015 cost reports to determine if the Worksheet S–10 data on those cost reports had changed as a result of the additional opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014 and FY 2015. Specifically, we compared hospitals' FY 2014 and FY 2015 Worksheet S–10 data as reported in the fourth quarter of CY 2016 update of HCRIS to the February 15, 2018 update of HCRIS. We examined hospitals' cost report data to determine if the Worksheet S–10 data had changed for any of the following lines: Total bad debt from Line 26, charity care for uninsured patients from Line 20, Column 1, or charity care for insured patients from Line 20, Column 2. Based on our review, we found that Worksheet S–10 data for both FY 2014 and FY 2015 had changed over that time period for approximately one-half of the hospitals that were eligible to receive Medicare DSH payments in FY 2018. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following the opportunity to review their previously submitted cost report data and submit a revised Worksheet S–10, and that this revised Worksheet S–10 information is available to be used in determining uncompensated care costs, contributes to our determination that it is appropriate to continue to incorporate Worksheet S–10 data into the calculation of Factor 3 values for hospitals that are eligible to receive Medicare DSH payments.

With the additional steps we have taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continue to believe that we can no longer conclude that alternative data to the Worksheet S–10 are currently available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, the actions that we have taken to improve the accuracy and consistency of the Worksheet S–10 data, including the opportunity for hospitals to resubmit Worksheet S–10 data for FY 2015, lead us to conclude that there are no alternative data to the Worksheet S–10 data currently available for FY 2015 that are a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals. As such, we are proposing to advance the time period of the data used in the calculation of Factor 3 forward by 1 year and to use data from FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019. For the reasons we described earlier, we continue to believe it is inappropriate to use Worksheet S–10 data for periods prior to FY 2014. Rather, for cost reporting periods prior to FY 2014, we believe it is appropriate to continue to use low-income insured days. Accordingly, with a time period that includes 3 cost reporting years consisting of FY 2015, FY 2014, and FY 2013, we are proposing to use Worksheet S–10 data for the FY 2014 and FY 2015 cost reporting periods and the low-income insured days proxy data for the earliest cost reporting period. As in previous years, in order to perform this calculation, we will draw three sets of data (1 year of Medicaid utilization data and 2 years of Worksheet S–10 data) from the most recent available HCRIS extract, which, is the HCRIS data updated through February 15, 2018, for purposes of this FY 2019 proposed rule. We expect to use the March 2018 update of HCRIS for the final rule. However, due to unique circumstances regarding the impact of the hurricanes in 2017 (Harvey, Irma, Maria, and Nate) and the extension of the deadline to resubmit Worksheet S–10 data through January 2, 2018, and the subsequent impact on the MAC review timeline, we may consider using data updated through May 31, 2018, in the final rule, if necessary.

Accordingly, for FY 2019, in addition to the Worksheet S–10 data for FY 2014 and FY 2015, we are proposing to use Medicaid days from FY 2013 cost reports and FY 2016 SSI ratios. We note that cost report data from Indian Health Service and Tribal hospitals are included in HCRIS beginning in FY 2013 and no longer need to be incorporated from a separate data source. We also are proposing to

continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers. In addition, we are proposing to continue the policies that were finalized in the FY 2018 IPPS/LTCH PPS final rule to address technical considerations related to the calculation of Factor 3 and the incorporation of Worksheet S–10 data (82 FR 38213 through 38220). With respect to the calculation of Factor 3, we adopted a policy under which we annualize Medicaid days data and uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data. As in FY 2018, for FY 2019, we are not proposing to annualize SSI days because we do not obtain these data from hospital cost reports in HCRIS. Rather, we obtain these data from the latest available SSI ratios posted on the Medicare DSH homepage (*https://www.cms.gov/Medicare/Medicare-fee-for-service-payment/AcuteInpatientPPS/dsh.html*), which are aggregated at the hospital level and do not include the information needed to determine if the data should be annualized. To address the effects of averaging Factor 3s calculated for 3 separate fiscal years, we apply a scaling factor to the Factor 3 values of all DSH eligible hospitals such that total uncompensated care payments are consistent with the estimated amount available to make uncompensated care payments for the applicable fiscal year. With respect to the incorporation of Worksheet S–10, we believe that the definition of uncompensated care adopted in FY 2018 is 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, and correlates to Line 30 of Worksheet S–10. Therefore, we are again proposing that, for purposes of calculating Factor 3 and uncompensated care costs in FY 2019, ''uncompensated care'' would 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 nonreimbursable Medicare bad debt (Line 29).

We note that we are proposing to discontinue the policy finalized in the FY 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year (81 FR 56957). Under this policy, we would first combine the data across the multiple cost reports before determining the difference between the start date and the end date to determine if annualization is needed. The policy was developed in response to commenters' concerns regarding the unique circumstances of hospitals that filed cost reports that are shorter or longer than 12 months. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56957 through 56959) and in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19953), we believed that, for hospitals that file multiple cost reports beginning in the same year, combining the data from these cost reports had the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. We now believe that concerns about the equitability of the data used as the basis of hospital uncompensated care payments are more thoroughly addressed by the policy finalized in the FY 2018 IPPS/LTCH PPS final rule, under which CMS annualizes the Medicaid days and uncompensated care cost data of hospital cost reports that do not equal 12 months of data. Based on our experience, we believe that in many cases where a hospital files two cost reports beginning in the same fiscal year, combining the data across multiple cost reports before annualizing would yield a similar result to choosing the longer of the two cost reports and then annualizing the data if the cost report is shorter or longer than 12 months. Furthermore, even in cases where a hospital files more than one cost report beginning in the same fiscal year, it is not uncommon for one of those cost reports to span exactly 12 months. In this case, if Factor 3 is determined using only the full 12-month cost report, annualization would be unnecessary as there would already be 12 months of data. Therefore, for FY 2019, we believe it is appropriate to propose to eliminate the additional step of combining data across multiple cost reports if a hospital filed more than one cost report beginning in the same fiscal year. Instead, for purposes of calculating Factor 3, we would use data from the cost report that is equivalent to 12 months or, if no such cost report exists, the cost report that is closest to 12 months and annualize the data. Furthermore, we acknowledge that, in rare cases, a hospital may have more than one cost report beginning in one fiscal year, where one report also spans the entirety of the following fiscal year such that the hospital has no cost report beginning in that fiscal year. For instance, a hospital's cost reporting period may have started towards the end of FY 2012 but cover the duration of FY 2013. In these rare situations, we are proposing to use data from the cost report that spans both fiscal years in the Factor 3 calculation for the latter fiscal year as the hospital would already have data from the preceding cost report that could be used to determine Factor 3 for the previous fiscal year.

We also are proposing to continue to apply statistical trims to anomalous hospital CCRs using the methodology adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38219), where we stated our belief that, just as we apply trims to hospitals' CCRs to eliminate anomalies when calculating outlier payments for extraordinarily high cost cases (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs on Worksheet S–10, Line 1, that are considered anomalies. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR ''ceiling''). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year.

Similar to the process used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38218) for trimming CCRs, we are proposing the following steps for FY 2019:

Step 1: Remove Maryland hospitals. In addition, we would remove All-Inclusive Rate Providers because they have charge structures that differ from other IPPS hospitals. For providers that did not report a CCR on Worksheet S–10, Line 1, we would assign them the statewide average CCR in step 5 below.

Step 2: For each fiscal year (FY 2014 and FY 2015), 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 FY is no longer necessary in this step, 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. (Based on the information currently available to us, this trim would remove 5 hospitals that have a CCR above the calculated ceiling of 1.031 for FY 2014 and 9 hospitals that have a CCR above the calculated ceiling of 0.93 for FY 2015.)

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2014 and for FY 2015 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total inpatient discharges and outpatient visits from Worksheet S–3, Part I, Line 14, Column 14.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals with a CCR for the applicable fiscal year greater than 3 standard deviations above the corresponding national geometric mean for that fiscal year (that is, the CCR ''ceiling''). The statewide average CCR would therefore be applied to 14 hospitals, of which 2 hospitals in FY 2014 have Worksheet S–10 data and 5 hospitals in FY 2015 have Worksheet S–10 data.

After applying the applicable trims to a hospital's CCR as appropriate, we would calculate a hospital's uncompensated care costs for the applicable fiscal year as being equal to Line 30, which is the sum of Line 23, Column 3 and Line 29, as follows:

Hospital Uncompensated Care Costs = Line 30 (Line 23, Column 3 + Line 29), which is equal to—

[(Line 1 CCR (as adjusted, if applicable) × Uninsured patient charity care Line 20, Column 1) − (Payments received from uninsured patient charity care Line 22, Column 1)] + [(Insured patient charity care Line 20, Column 2) − Insured patient charges from days beyond length of stay limit * (1 − (Line 1 CCR (as adjusted, if applicable))) − (Payments received from insured patient charity care Line 22, Column 2)] + [(Line 1 CCR (as adjusted, if applicable) × Non-Medicare bad debt Line 28) + (Medicare allowable bad debts Line 27.01 − Medicare reimbursable bad debt Line 27)].

Similar in concept to the policy that we adopted for FY 2018, for FY 2019, we continue to believe that uncompensated care costs that represent an extremely high ratio of a hospital's total operating expenses (such as the ratio of 50 percent used in the FY 2018 IPPS/LTCH PPS final rule) may be potentially aberrant, and that using the ratio of uncompensated care costs to total operating costs to identify potentially aberrant data when determining Factor 3 amounts has merit. That is, we continue to believe that, in the rare situations where a hospital has a ratio of uncompensated care costs to total operating expenditures that is extremely high, the issue is most likely with the hospital's uncompensated care costs and not its total operating costs. We have instructed the MACs to review situations where a hospital has an extremely high ratio of uncompensated care costs to total operating costs with the hospital. We do not intend to make the MACs' review protocols public. As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56964), for program integrity reasons, CMS desk review and audit protocols are confidential and are for CMS and MAC use only. If the hospital cannot justify its reported uncompensated care amount, we believe it would be appropriate to utilize data from another fiscal year to address the potentially aberrant Worksheet S–10 data for FY 2014 or FY 2015. As we have previously indicated, we do not believe it would be appropriate to use Worksheet S–10 data from years prior to FY 2014 in the determination of Factor 3. Therefore, the most widely available Worksheet S–10 data available to us if a hospital has an extremely high ratio of uncompensated care costs to total operating expenses based on its FY 2014 or FY 2015 Worksheet S–10 data are the FY 2015 and FY 2016 Worksheet S–10 data. Accordingly, similar in concept to the approach we used in FY 2018, in cases where a hospital's uncompensated care costs for FY 2014 are an extremely high ratio of its total operating costs and the hospital cannot justify the amount it reported, we are proposing to determine the ratio of FY 2015 uncompensated care costs to FY 2015 total operating expenses from the hospital's FY 2015 cost report and apply that ratio to the FY 2014 total operating expenses from the hospital's FY 2014 cost report to determine an adjusted amount of uncompensated care costs for FY 2014. We would then use this adjusted amount to determine Factor 3 for FY 2019. Similarly, if a hospital has uncompensated care costs for FY 2015 that are an extremely high ratio of its total operating costs for that year and the hospital cannot justify its reported amount, we are proposing to follow the same methodology using data from the hospital's FY 2016 cost report to determine an adjusted amount of uncompensated care costs for FY 2015. That is, we would determine the ratio of FY 2016 uncompensated care costs to FY 2016 total operating expenses from a hospital's FY 2016 cost report and apply that ratio to the FY 2015 total operating expenses from the hospital's FY 2015 cost report to determine an adjusted amount of uncompensated care costs for FY 2015. We would then use this adjusted amount when determining Factor 3 for FY 2019. We have tentatively included the data for hospitals that have a high ratio of uncompensated care costs to total operating expenses when calculating Factor 3 for this proposed rule. We note, however, that our calculation of Factor 3 for the final rule will be contingent on the results of the ongoing MAC reviews of these hospitals. In the event those reviews necessitate supplemental data edits, we would incorporate such edits in the final rule for the purpose of correcting aberrant data.

For FY 2019, we also believe that situations where there were extremely large dollar increases or decreases in a hospital's uncompensated care costs when it resubmitted its FY 2014 Worksheet S–10 or FY 2015 Worksheet S–10 data, or when the data it had previously submitted were reprocessed by the MAC, may reflect potentially aberrant data and warrant further review. For example, although we do not make our actual review protocols public, we might conclude that it would be appropriate to review hospitals with increases or decreases in uncompensated care costs in the top 1 percent of such changes. We have instructed our MACs to review these situations with each hospital. If it is determined after this review that an increase or decrease in uncompensated care costs cannot be justified by the hospital, we are proposing to follow the same approach that we are proposing to use to address situations when a hospital's ratio of its uncompensated care costs to its operating expenses is extremely high and the hospital cannot justify its reported amount. Specifically, if after review, the increase or decrease in uncompensated care costs for FY 2014 or FY 2015 cannot be justified by the hospital, we would determine the ratio of the uncompensated care costs to total operating expenses from the hospital's cost report for the subsequent fiscal year and apply that ratio to the total operating expenses from the hospital's resubmitted cost report with the large increase or decrease in uncompensated care payments to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. We have tentatively included the data for

hospitals where there was an extremely large increase or decrease in uncompensated care payments when calculating Factor 3 for this proposed rule. However, we note that our calculation of Factor 3 for the final rule will be contingent on the results of the ongoing MAC reviews of these hospitals. In the event those reviews necessitate supplemental data edits, we would incorporate such edits in the final rule for the purpose of correcting aberrant data.

For Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and All-Inclusive Rate Providers, we are proposing to continue 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, we continue 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 (82 FR 38209). Finally, the CCRs for All-Inclusive Rate Providers are potentially erroneous and still in need of further examination before they can be used in the determination of uncompensated care amounts for purposes of Factor 3 (82 FR 38212). For the reasons described earlier related to the impact of the Medicaid expansion beginning in FY 2014, we also continue to believe that it is inappropriate to calculate a Factor 3 using FY 2014 and FY 2015 low-income insured days. Because we do not believe it is appropriate to use the FY 2014 or FY 2015 uncompensated care data for these hospitals and we also do not believe it is appropriate to use the FY 2014 or FY 2015 low-income insured days, the best proxy for the costs of Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and All-Inclusive Rate Providers for treating the uninsured continues to be the low-income insured days data for FY 2013. Accordingly, for these hospitals, we are proposing to determine Factor 3 only on the basis of low-income insured days for FY 2013. We believe this approach is appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. We are not making any proposals with respect to the calculation of Factor 3 for FY 2020 and will reexamine the use of the Worksheet S–10 data for Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and All-Inclusive Rate Providers as part of the FY 2020 rulemaking. In addition, because we are continuing to use 1 year of insured low-income patient days as a proxy for uncompensated care and residents of Puerto Rico are not eligible for SSI benefits, we are proposing to continue to use a proxy for SSI days consisting of 14 percent of a hospital's Medicaid days for Puerto Rico hospitals, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2019, we are proposing to compute Factor 3 for each hospital by—

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and All-Inclusive Rate Providers using the Factor 3 value from Step 1).

We also are proposing to amend the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (*5*) to reflect this proposed methodology for computing Factor 3 for FY 2019.

We note that, if a hospital does not have both Medicaid days for FY 2013 and SSI days for FY 2016 available for use in the calculation of Factor 3 in Step 1, we consider the hospital not to have data available for the fiscal year, and will remove that fiscal year from the calculation and divide by the number of years with data. A hospital will be considered to have both Medicaid days and SSI days data available if it reports zero days for either component of the Factor 3 calculation in Step 1. However, if a hospital is missing data due to not filing a cost report in one of the applicable fiscal years, we will divide by the remaining number of fiscal years.

Although we are not making any proposals with respect to the development of Factor 3 for FY 2020 and subsequent fiscal years, the above methodology would have the effect of fully transitioning the incorporation of data from Worksheet S–10 into the calculation of Factor 3 if used in FY 2020. Starting with 1 year of Worksheet S–10 data in FY 2018, an additional year of Worksheet S–10 data could be incorporated into the calculation of Factor 3 in FY 2019 if our proposed methodology is finalized, and the use of low-income insured days would be phased out by FY 2020 if the same methodology is proposed and finalized for that year. It is also possible that when we examine the FY 2016 Worksheet S–10 data, we may determine that the use of multiple years of Worksheet S–10 data is no longer necessary in calculating Factor 3 for FY 2020.

For new hospitals that do not have data for any of the three cost reporting periods used in the Factor 3 calculation, we are proposing to continue to apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643). That is, the hospital would not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. However, if the hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2019 cost report, the hospital would also 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 2019 cost report, and the denominator is the sum of uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' FY 2015 cost reports. Due to the uncertainty regarding the completeness and accuracy of the FY 2019 uncompensated care cost data at the time this calculation would need to be performed, we believe it would be more appropriate to use the sum of the uncompensated care costs reported on Worksheet S–10 of all DSH eligible hospitals' cost reports from FY 2015, the most recent year of the 3-year time period used in the development of Factor 3, to determine the denominator of Factor 3 for new hospitals. We note 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.

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with both the FY 2019 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 2019 (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 the development of this proposed rule, the FY 2016 SSI ratios were available. Accordingly, for modeling purposes, we computed the proposed Factor 3 for each hospital using the most recent available data regarding SSI days from the FY 2016 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 2019 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of any inaccuracies. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We will address these comments as appropriate in the table and the supplemental data file that we will publish on the CMS website in conjunction with the publication of the FY 2019 IPPS/LTCH PPS final rule. After the publication of the FY 2019 IPPS/LTCH PPS final rule, hospitals will have until August 31, 2018, to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. Comments may be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2018, and any changes to Factor 3 will be posted on the CMS website prior to October 1, 2018.

We are inviting public comments on our proposed methodology for calculating Factor 3 for FY 2019, including, but not limited to, our proposed use of the FY 2013 low-income insured days proxy data, and the FY 2014 and FY 2015 Worksheet S–10 data.

G. Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs) (§§ 412.90, 412.92, and 412.108)

1. Background on SCHs and MDHs

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).

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, or is located in an all-urban State but meets one of the specified statutory criteria for rural reclassification (as added by section 50205 of the Bipartisan Budget Act of 2018, Pub. L. 115–123), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH. For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).

2. Implementation of Legislation Relating to the MDH Program

a. Legislative Extension of the MDH Program

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended by subsequent legislation. Most recently, section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for FYs 2018 through 2022 (that is, for discharges occurring before October 1, 2022). (Additional information on the extensions of the MDH program after FY 2012 and through FY 2017 can be found in the FY 2016 interim final rule with comment period (80 FR 49596).)

Section 50205 of the Bipartisan Budget Act of 2018 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program for discharges occurring on or after October 1, 2017, through FY 2022 (that is, for discharges occurring on or before September 30, 2022).

We note that, consistent with the previous extensions of the MDH program, generally, a provider that was classified as an MDH as of September 30, 2017, was reinstated as an MDH effective October 1, 2017, with no need to reapply for MDH classification. However, if the MDH had classified as an SCH or cancelled its rural classification under § 412.103(g) effective on or after October 1, 2017, the effective date of MDH status may not be retroactive to October 1, 2017. We refer readers to the notice (CMS–1677–N) that appears elsewhere in this issue of the **Federal Register** for more information on the MDH extension in FY 2018.

b. MDH Classification for Hospitals in All-Urban States

In addition to extending the MDH program, section 50205 amended section 1886(d)(5)(G)(iv) of the Act to include in the definition of an MDH a hospital that is located in a State with no rural area (as defined in paragraph (2)(D)) and satisfies any of the criteria in section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act, in addition to the other qualifying criteria.

Section 50205 of the Bipartisan Budget Act of 2018 also amended section 1886(d)(5)(G)(iv) of the Act by adding a provision following section 1886(d)(5)(G)(iv)(IV), which specifies that new section 1886(d)(5)(G)(iv)(I)(bb) of the Act applies for purposes of the MDH payment under sections 1886(d)(5)(G)(ii) of the Act (that is, 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years) only for discharges of a hospital occurring on or after the effective date of a determination of MDH status made with respect to the hospital after the date of the enactment of this provision. We note that, under existing regulations, the effective date for a determination of MDH status is 30 days after the date the MAC provides written notification of MDH status. We

also note that we are proposing in section IV.G.3. of the preamble of this proposed rule to change the effective date for a determination of MDH status. If the proposal is finalized, the policy would not be effective until FY 2019 (October 1, 2018) and therefore would not apply to hospitals applying for MDH classification before October 1, 2018. Furthermore, this new provision also specifies that, for purposes of new section 1886(d)(5)(G)(iv)(I)(bb) of the Act, section 1886(d)(8)(E)(ii)(II) of the Act shall be applied by inserting ''as of January 1, 2018,'' after ''such State'' each place it appears. Section 50205 of the Bipartisan Budget Act also made conforming amendments to sections 1886(b)(3)(D) (in the language proceeding clause (i)) and 1886(b)(3)(D)(iv) of the Act.

Section 1886(d)(8)(E) of the Act provides for an IPPS hospital that is located in an urban area to be reclassified as a rural hospital if it submits an application in accordance with CMS' established process and meets certain criteria at section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (these statutory criteria are implemented in the regulations at § 412.103(a)(1) through (3)). A subsection (d) hospital that is located in an urban area and meets one of the three criteria under § 412.103(a) can reclassify as rural and is treated as being located in the rural area of the State in which it is located. However, a hospital that is located in an all-urban State is ineligible to reclassify as rural in accordance with the provisions of § 412.103 because the State in which it is located does not have a rural area into which it can reclassify. Prior to the amendments made by the Bipartisan Budget Act, a hospital could only qualify for MDH status if it was either geographically located in a rural area or if it reclassified as rural under the regulations at § 412.103. This precluded hospitals in all-urban States from being classified as MDHs. The newly added provision in the Bipartisan Budget Act of 2018 allows a hospital in an all-urban State to be eligible for MDH classification if, in addition to meeting the other criteria for MDH eligibility, it satisfies one of the criteria for rural reclassification under section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (as of January 1, 2018, where applicable), notwithstanding its location in an all-urban State.

As noted earlier, prior to the enactment of the Bipartisan Budget Act of 2018, a hospital in an all-urban State was ineligible for MDH classification because it could not reclassify as rural. With the new provision added by section 50205 of the Bipartisan Budget Act of 2018, a hospital in an all-urban State can apply and be approved for MDH classification if it can demonstrate that: (1) It meets the criteria at § 412.103(a)(1) or (3) or the criteria at § 412.103(a)(2) as of January 1, 2018, for the sole purposes of qualifying for MDH classification; and (2) it meets the MDH classification criteria at § 412.108(a)(1)(i) through (iii), which, as amended, would be redesignated as § 412.108(a)(1)(i) through (iv). We note that for a hospital in an all-urban State to demonstrate that it would have qualified for rural reclassification notwithstanding its location in an all-urban State (as of January 1, 2018, where applicable), it must follow the applicable procedures for rural reclassification and MDH classification at § 412.103(b) and § 412.108(b), respectively. We also note that we are not proposing any changes to the reclassification criteria under § 412.103 and that a hospital in an all-urban State that qualifies as an MDH under the newly added statutory provision will not be considered as having reclassified as rural but only as having satisfied one of the criteria at section 1886(d)(8)(E)(ii)(I), (II), or (III) of the Act (as of January 1, 2018, as applicable) for purposes of MDH classification, in accordance with amended section 1886(d)(5)(G)(iv) of the Act.

We are proposing to make conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extension of the MDH program for FY 2018 through FY 2022 and the additional MDH classification provision made for hospitals located in all-urban States by section 50205 of the Bipartisan Budget Act of 2018. We are proposing a similar conforming change to § 412.90(j) to reflect the extension of the MDH program through FY 2022.

3. Proposal Regarding Change to SCH and MDH Classification Status Effective Dates

The regulations at 42 CFR 412.92(b)(2)(i) set forth an effective date for SCH classification of 30 days after the date of CMS' written notification of approval. Similarly, § 412.92(b)(2)(iv) specifies that a hospital classified as an SCH receives a payment adjustment effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification.

Section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113, Appendix F) amended section 1886(d)(8) of the Act to add paragraph (E) which authorizes reclassification of certain urban hospitals as rural if the hospital applies for such status and meets certain criteria. The effective date for rural reclassification status under section 1886(d)(8)(E) of the Act is set forth at 42 CFR 412.103(d)(1) as the filing date, which is the date CMS receives the reclassification application (§ 412.103(b)(5)). One way that an urban hospital can reclassify as rural under § 412.103 (specifically, § 412.103(a)(3)) is if the hospital would qualify as a rural referral center (RRC) as set forth in § 412.96, or as an SCH as set forth in § 412.92, if the hospital were located in a rural area. A geographically urban hospital may simultaneously apply for reclassification as rural under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and apply to obtain SCH status under § 412.92 based on that acquired rural reclassification. However, the rural reclassification is effective as of the filing date, while the SCH status is effective 30 days after approval. In addition, while § 412.103(c) states that the CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date, the regulations do not set a timeframe by which CMS must decide on an SCH request. Therefore, geographically urban hospitals that obtain rural reclassification under § 412.103 for the purposes of obtaining SCH status may face a payment disadvantage because they are paid as rural until the SCH application is approved and the SCH classification and payment adjustment become effective 30 days after approval.

To minimize the lag between the effective date of rural reclassification under § 412.103 and the effective date for SCH status, we are proposing to revise § 412.92(b)(2)(i) and (b)(2)(iv) so that the effective date for SCH classification and for the payment adjustment would be the date that CMS receives the complete SCH application, effective for SCH applications received on or after October 1, 2018. A complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for SCH status as of the date of application, which includes documentation of rural reclassification in the case of a geographically urban hospital. For an application to be complete, all criteria must be met as of the date CMS receives the SCH application. For example, a hospital applying for SCH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its SCH application in order to be considered rural as of the date CMS receives the SCH application.

Similar to rural reclassification obtained under § 412.103, the effective date for SCH status would be the date that CMS receives the complete application. We also are proposing conforming changes to the effective date at § 412.92(b)(2)(ii) for instances when a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses a CMS denial of SCH status and no further appeal is made. In the interest of a clear and consistent policy, we are proposing that this change in the SCH effective date would also apply for hospitals not reclassifying as rural under § 412.103, such as geographically rural hospitals obtaining SCH status. We believe that these proposals to update the regulations at § 412.92 to provide an effective date for SCH status that is consistent with the effective date for rural reclassification under § 412.103 would benefit hospitals by minimizing any payment disadvantage caused by the lag between the effective date of rural reclassification and the effective date of SCH status. We also believe this proposal to align the SCH effective date with the § 412.103 effective date supports agency efforts to reduce regulatory burden because it would provide for a more uniform policy.

In addition, we are proposing to make parallel changes to the effective date for an MDH status determination under § 412.108(b)(4). As discussed earlier, section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program through FY 2022 by amending section 1886(d)(5)(G) of the Act. Similar to the proposed change in effective date for SCH status approvals, we are proposing that a determination of MDH status would be effective as of the date that CMS receives the complete application, for applications received on or after October 1, 2018, rather than the current effective date at § 412.108(b)(4) of 30 days after the date the MAC provides written notification to the hospital. Similar to applications for SCH status, a complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for MDH status as of the date of application. For an application to be complete, all criteria must be met as of the date CMS receives the MDH application. For example, a cost report must be settled at the time of application for a hospital to use that cost report as one of the cost reports required in § 412.108(a)(1)(iii)(C), and a hospital applying for MDH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its MDH application in order to be considered rural as of the date CMS receives the MDH application. (We note that a hospital in an all-urban State that applies for MDH status under the expanded definition at section 50205 of the Bipartisan Budget Act of 2018 would need to submit its application for a determination that it meets the criteria at § 412.103(a)(1) or (3) or the criteria at § 412.103(a)(2) as of January 1, 2018 (as discussed in the previous section) no later than its MDH application in order for the application to be considered complete.)

We believe that concurrently changing the SCH and MDH status effective dates from 30 days after the date of approval to the date the complete application is received would allow for consistency in the regulations governing effective dates of special rural hospital status. In addition, this proposal would benefit urban hospitals that are requesting § 412.103 rural reclassification at the same time as MDH status because it would synchronize effective dates to eliminate any payment consequences caused by a lag between effective dates for rural reclassification and MDH status.

4. Proposed Conforming Technical Changes to Regulations

We note that, in this proposed rule, we also are proposing to make technical conforming changes to the regulations in § 412.92 and § 412.108 to reflect the change CMS made some time ago to identify fiscal intermediaries as Medicare administrative contractors (MACs).

H. 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 added by section 3025 of the Affordable Care Act as amended by section 10309 of the Affordable Care Act, and further amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the 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 peer groups of hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions. We refer readers to section IV.E.1. of the preamble of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and section V.I.1. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR38221 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); and
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).

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 calculation of the excess readmission ratio, which is used, in part, to calculate the payment adjustment factor; (3) beginning in FY 2018, the calculation of the proportion of ''dually eligible'' Medicare beneficiaries (described below) which is used to stratify hospitals into peer groups and establish the peer group median excess readmission ratios (ERRs); (4) 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; (5) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare;* (6) the adoption of an extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (7) the clarification that the public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* website as soon as is feasible following the Review and Correction period; and (8) 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 Puerto Rico.

We also have codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

The Hospital Readmissions Reduction 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 costs and allows clinicians to focus on providing high quality health care 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 Readmissions Reduction Program incentivizes hospitals to improve health care quality and value, while giving patients the tools and information needed to make the best decisions for them.

3. Summary of Proposed Policies for the Hospital Readmissions Reduction Program

In this proposed rule, we are proposing to: (1) Establish the applicable period for FY 2019, FY 2020 and FY 2021; (2) codify the previously adopted definition of ''dual-eligible''; (3) codify the previously adopted definition of ''proportion of dual-eligibles''; and (4) codify the previously adopted definition of ''applicable period for dual-eligibility.''

These proposals are described in more detail below.

4. Current Measures for FY 2019 and Subsequent Years

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG).

By publicly reporting quality data, we strive to put patients first, ensuring they, along with their clinicians, are empowered to make decisions about their own healthcare using information aligned with a meaningful quality measures. The Hospital Readmissions Reduction Program, together with the Hospital VBP Program and the HAC Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing to the inpatient care setting. We have undertaken efforts to review the existing measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative we described in section I.A.2. of the preamble of this proposed rule.

As part of this review, we have taken a holistic approach to evaluating the appropriateness of the Hospital Readmissions Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital VBP Program and the HAC Reduction Program), as well as the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable,—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

Measures in the Hospital Readmissions Reduction Program are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting. By including these measures in the Program, we seek to encourage hospitals to address the serious problems indicated by the necessity of a hospital readmission and to reduce them and improve care coordination and communication. Therefore, after thoughtful review, we have determined that the six readmission measures in the Hospital Readmissions Reduction Program, which we are proposing for removal from the Hospital IQR Program in section VIII.A.5.b.(3) of the preamble of this proposed rule, are nevertheless appropriately included as part of the Hospital Readmissions Reduction Program.

We continue to believe that the measures that we have adopted adequately address the conditions and procedures specified in the Hospital Readmissions Reduction Program statute. Therefore, we are not proposing to adopt any new measures at this time.

5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our website in

the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet website on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995.*

6. Proposed Applicable Periods for FY 2019, FY 2020, and FY 2021

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and payment adjustment factors for the fiscal year, which 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 Program.

In this proposed rule, for FY 2019, consistent with the definition specified at § 412.152, we are proposing that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2014 through June 30, 2017. In other words, we are proposing that the proportion of dual-eligibles, excess readmissions ratios and the payment adjustment factors (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2019 would be calculated using data for discharges occurring during the 3-year time period of July 1, 2014 through June 30, 2017.

In this proposed rule, for FY 2020, consistent with the definition specified at § 412.152, we are proposing that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2015 through June 30, 2018. As noted earlier, we define the applicable period for dual-eligibles as the applicable period that we otherwise adopted for purposes of the Program; therefore, for FY 2020, the applicable period for dual-eligibles would be the 3-year period from July 1, 2015 through June 30, 2018.

In addition, in this proposed rule, for FY 2021, consistent with the definition specified at § 412.152, we are proposing that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2016 through June 30, 2019. The applicable period for dual-eligibles for FY 2021 would similarly be the 3-year period from July 1, 2016 through June 30, 2019.

We are inviting public comments on these proposals.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges

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 such 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 2019 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, since diagnoses and procedure codes for discharges occurring prior to October 1, 2015 were reported under the ICD–9–CM code set, while discharges occurring on or after October 1, 2015 (FY 2016), were reported under the ICD–10–CM and ICD–10–PCS code sets.

We only identify Medicare Fee-for-Service (FFS) claims that meet the criteria described above for each applicable condition/procedure to calculate the aggregate payments for excess readmissions (that is, claims paid for under Medicare Part C or Medicare Advantage, are not included in this calculation). This policy is consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2019, we are proposing to continue to exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database.

In this proposed rule, for FY 2019, we are proposing to determine aggregate payments for excess readmissions, aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2014, and no later than June 30, 2017. 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 2019 readmissions payment adjustment factors for this proposed rule, we are using the proportion of dual-eligibles, excess readmissions ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2018 Hospital Readmissions Reduction Program applicable period. For the FY 2019 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2019 applicable period of July 1, 2014 to June 30, 2017, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate 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, for FY 2019, we are proposing to use MedPAR data from July 1, 2014 through June 30, 2017 for FY 2019 Hospital Readmissions Reduction Program calculations. Specifically—

- March 2015 update of the FY 2014 MedPAR file to identify claims within FY 2014 with discharges dates that are on or after July 1, 2014;
- March 2016 update of the FY 2015 MedPAR file to identify claims within FY 2015;
- March 2017 update of the FY 2016 MedPAR file to identify claims within FY 2016;
- March 2018 update of the FY 2017 MedPAR file to identify claims within FY 2017.

We are inviting public comments on this proposal.

8. Calculation of Payment Adjustment Factors for FY 2019 and Proposed Codification of Certain Definitions

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.

To implement this provision, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237), we finalized a number of changes to the payment adjustment methodology for FY 2019. First, we finalized that an individual would be counted as a full-benefit dual-eligible 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 (82 FR 38226 through 38228). Second, we finalized our policy to define the proportion of full benefit dual-eligible beneficiaries as the proportion of dual-eligible patients among all Medicare FFS and Medicare Advantage stays (82 FR 38226 through 38228). Third, we finalized our policy to define the data period for determining dual-eligibility as the 3-year data period corresponding to the Program's applicable period (82 FR 38229). Fourth, we finalized our policy to stratify hospitals into quintiles, or five peer groups, based on their proportion of dual-eligible patients (82 FR 38229 through 38231). Finally, we finalized our policy to use the median Excess Readmission Ratio (ERR) for the hospital's peer group in place of 1.0 in the payment adjustment formula and apply a uniform modifier to maintain budget neutrality (82 FR 38231 through 38237). The payment adjustment formula would then be:

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM * Payment(dx) * \max\{(\text{ERR(dx)} - \text{Median peer group ERR(dx)}),0\})}{All\ payments}\}$$

where dx is AMI, HF, pneumonia, COPD, THA/TKA or CABG and payments refers to the base operating DRG payments. The payment reduction (1–P) resulting from use of the median ERR for the peer group is scaled by a neutrality modifier (NM) to achieve budget neutrality. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the changes to the payment adjustment methodology, including alternatives considered, for FY 2019. We are not proposing any changes to the methodology for FY 2019 or subsequent years. However, we are proposing to codify our previously finalized definitions of ''applicable period for dual-eligibility'', ''dual-eligible'', and ''proportion of dual-eligibles'' at 42 CFR 412.152. The definitions which we are proposing to codify are as follows:

- Applicable period for dual-eligibility is the 3-year data period corresponding to the applicable period as established by the Secretary for the Hospital Readmissions Reduction Program.
- Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State MMA files for the month the beneficiary was discharged from the hospital.
- Proportion of dual-eligibles is the number of dual-eligible patients among all Medicare FFS and Medicare Advantage stays during the applicable period.

We are inviting public comment on our proposal to codify these definitions.

9. Proposed Calculation of Payment Adjustment for FY 2019

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—(i) the aggregate payments for excess readmissions, and (ii) the aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. 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 § 412.154(c)(2), for FY 2019, 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 2019, 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).

We are inviting public comments on these proposals regarding the calculation of payment adjustment factors for FY 2019.

10. Accounting for Social Risk Factors in the Hospital Readmissions Reduction Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237 through 38239), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[250] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[251] As we noted in the FY

[250] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[251] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016.

2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[252] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.* The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[253] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

I. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care 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); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38240 through 38269).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2019 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)(iv) of the Act, the applicable percent for the FY 2019 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 2019 is approximately $1.9 billion, based on the December 2017 update of the FY 2017 MedPAR file. We intend to update this estimate for the FY 2019 IPPS/LTCH PPS final rule using the March 2018 update of the FY 2017 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

Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[252] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[253] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

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 2019, 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 TPS from the FY 2018 program year. These FY 2018 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 2.8888347029. This slope, along with the estimated amount available for value-based incentive payments is also published in Table 16 (which is available via the internet on the CMS website).

We intend to update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2018 update to the FY 2017 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 2019 will continue to be based on historic FY 2018 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2019 program year until after the FY 2019 IPPS/LTCH PPS final rule is published.

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2019, we will post Table 16B (which will be available via the internet on the CMS website) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2019 program year. We expect Table 16B will be posted on the CMS website in the fall of 2018.

2. Retention and Proposed Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Proposal To Clarify the 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 this proposed rule, we are not proposing any changes to this policy.

We are, however, proposing to revise 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* for at least one year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP statute does not require that the measure continue to remain in the Hospital IQR Program. The proposed revision to the regulation text would clarify that Hospital VBP measures will be selected from the measures specified under the Hospital IQR Program, but the Hospital VBP Program measure set will not necessarily be a subset of the Hospital IQR Program measure set. As discussed in section I.A.2. of the preamble of this proposed rule, we are engaging in efforts aimed at evaluating and streamlining regulations with the goal to reduce unnecessary costs, increase efficiencies, and improve beneficiary experience. This proposal would reduce costs, such as those discussed in section IV.I.2.b. of the preamble of this proposed rule, by allowing us to remove duplicative measures from the Hospital IQR Program that are retained in the Hospital VBP Program.

We are inviting comment on this proposal.

b. Proposed Measure Removal Factors for the Hospital VBP Program

As discussed earlier, we have adopted a policy to generally retain measures from prior year's Hospital VBP Program for subsequent years' measure sets unless otherwise proposed and finalized. We have previously removed measures from the Hospital VBP Program for reasons such as being topped out (80 FR 49550), the measure does not align with current clinical guidelines or practices (78 FR 50680 through 50681), a more applicable measure was available (82 FR 38242 through 38244), there was insufficient evidence that the measure leads to better outcomes (78 FR 50680 through 50681), another measure was more closely linked to better outcomes (77 FR 53582 through 53584, and 53592), unintended consequences (82 FR 38242 through 38244), and impossibility of calculating a score (82 FR 38242 through 38244).

The reasons we cited above to support the removal of measures from the Hospital VBP Program generally align with measure removal factors that have been adopted by the Hospital IQR Program. We believe that these factors are also applicable in evaluating Hospital VBP Program quality measures for removal, and that their adoption in the Hospital VBP Program will help ensure consistency in our measure evaluation methodology across our programs. Accordingly, we are proposing to adopt the Hospital IQR Program measure removal factors that we finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and further refined in the FY 2015 IPPS/LTCH PPS and FY 2016 IPPS/LTCH PPS final rules (79 FR 50203 through 50204 and 80 FR 49641 through 49643, respectively) for use in determining whether to remove Hospital VBP Program measures:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures), defined as: Statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10; [254]
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic);
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- Factor 7. It is not feasible to implement the measure specifications.

We note that these removal factors would be considerations taken into account when deciding whether or not to remove measures, not firm requirements. We continue to believe that there may be circumstances in which a measure that meets one or more factors for removal should be retained regardless, because the drawbacks of removing a measure could be outweighed by other benefits to retaining the measure.

[254] We previously adopted the two criteria for determining the ''topped-out'' status of Hospital VBP Program measures in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50055).

Also in alignment with proposals being made for other quality reporting and value-based purchasing programs, we are proposing to adopt the following additional factor to consider when evaluating measures for removal from the Hospital VBP Program measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the preamble of this proposed rule with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the Hospital VBP Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the Hospital VBP Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the Hospital VBP Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the Hospital VBP Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposals to adopt for the Hospital VBP Program the measure removal factors currently adopted in the Hospital IQR Program, and a measure removal factor where ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' beginning with FY 2019.

In addition, to further align with policies adopted in the Hospital IQR Program (74 FR 43864), we are proposing that if we believe continued use of a measure in the Hospital VBP Program poses specific patient safety concerns, we may promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure along with the reasons for its removal through routine communication channels to hospital, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. We would then confirm the removal of the measure from the Hospital VBP Program measure set in the next IPPS rulemaking. In circumstances where we do not believe that continued use of a measure raises specific patient safety concerns, we would use the regular rulemaking process to remove a measure.

We are inviting public comment on our proposal to allow the Hospital VBP Program to promptly remove a measure without rulemaking if we believe the measure poses specific patient safety concerns.

c. Proposed Removal of Ten Measures From the Hospital VBP Program

By publicly reporting quality data, we strive to put patients first, ensuring they, along with their clinicians, are empowered to make decisions about their own healthcare using information that are aligned with meaningful quality measures. The Hospital VBP Program, together with the Hospital Readmissions Reduction Program and the HAC Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing to the inpatient care setting. We have undertaken efforts to review the existing Hospital VBP Program measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative we describe in section I.A.2. of the preamble of this proposed rule.

As part of this review, we have taken a holistic approach to evaluating the appropriateness of the Hospital VBP Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital Readmissions Reduction Program and the HAC Reduction Program), as well as in the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable, but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective

communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.

As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

In this proposed rule, we are proposing to remove the following 10 measures previously adopted for the Hospital VBP Program:

- Elective Delivery (NQF #0469) (PC–01);
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);
- American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDI);
- Patient Safety and Adverse Events (Composite) (NQF #0531) (PSI 90); [255]
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

(1) Proposed Removal of PC–01: Elective Delivery (NQF #0469)

We are proposing to remove the Elective Delivery (NQF #0469) (PC–01) measure beginning with the FY 2021 program year because the costs associated with the measure outweigh the benefit of its continued use in the program—proposed removal Factor 8. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38262), we finalized both the benchmark at 0.000000 and the achievement threshold at 0.000000 for the PC–01 measure for the FY 2020 program year, meaning that at least 50 percent of hospitals that met the case minimum performed 0 elective deliveries for the measure during the baseline period of CY 2016. 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 50080 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. Based on past performance on the measure, we anticipate that continued use of the PC–01 measure in the Hospital VBP Program would result in more than half of hospitals with a calculable score for this measure earning the maximum 10 achievement points. We anticipate that the remaining hospitals with a calculable score would be awarded points based on improvement only because they will not have met the achievement threshold, earning zero to nine improvement points. Therefore, we believe the measure no longer meaningfully differentiates performance among most participating hospitals for scoring purposes in the Hospital VBP Program.

We continue to believe that avoiding early elective delivery is important; however, because overall performance on the PC–01 measure has improved over time and we anticipate the measure will have little meaningful effect on the TPS for most hospitals, we believe the measure is no longer appropriate for the Hospital VBP Program. In order to continue tracking and reporting rates of elective deliveries to incentivize continued high performance on the measure, this measure would remain in the Hospital IQR Program. We believe that maintaining the measure in the Hospital IQR Program, which publicly reports measure performance, will be sufficient to incentivize continued high performance or improvement on the measure. At the same time, we believe that removing the measure from the Hospital VBP Program will reduce costs and potential confusion for providers and clinicians to track the measure in both the Hospital IQR and Hospital VBP Programs, which may include reviewing different reports and tracking slightly different measure rates across programs.

Based on the reasons described above, we believe that under the measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, which we are proposing in section IV.I.2.b. of the preamble of this proposed rule, the costs of keeping the PC–01 measure in the Hospital VBP Program outweigh the benefits because the measure is costly for health care providers and clinicians to review multiple reports on this measure that is being retained in the Hospital IQR Program and our analyses show that the measure no longer meaningfully differentiates performance among participating hospitals for scoring purposes in the Hospital VBP Program.

Therefore, we are proposing to remove the PC–01 measure from the Hospital VBP Program beginning with the FY 2021 program year, with data collection on this measure for purposes of the Hospital VBP Program ending with December 31, 2018 discharges, based on proposed removal Factor 8—because the costs associated with the measure outweigh the benefit of its continued use in the program.

We are inviting public comment on this proposal to remove the Elective Delivery (NQF #0469) (PC–01) measure from the Hospital VBP Program as well as feedback on whether there are

[255] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS programs.

reasons to retain the measure in the Hospital VBP Program.

(2) Proposed Removal of Healthcare-Associated Infection (HAI) Measures and the Patient Safety and Adverse Events (Composite) Measure

We are proposing to remove the following five measures of healthcare-associated infections (HAIs) from the Hospital VBP Program beginning with the FY 2021 program year because the costs associated with the measures outweigh the benefit of their continued use in the program—proposed removal Factor 8:

- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (CAUTI);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (CLABSI);
- American College of Surgeons-Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSI);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) (MRSA Bacteremia); and
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (CDI).

We are also proposing to remove the Patient Safety and Adverse Events (Composite) (PSI 90) (NQF #0531) because the costs associated with the measure outweigh the benefit of its continued use in the program—proposed removal Factor 8.

As discussed in section IV.I.2.b. of the preamble of this proposed rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. While we continue to consider patient safety and reducing HAIs as high priorities (as reflected in the Meaningful Measures Initiative quality priority of making care safer by reducing harms caused in the delivery of care), the six measures listed above are all used in the HAC Reduction Program, which specifically focuses on reducing hospital-acquired conditions and improving patient safety outcomes. While there are differences in the scoring methodology between the Hospital VBP Program and the HAC Reduction Program, the HAC Reduction Program's incentive payment structure, like the Hospital VBP Program, ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected measures, thereby incentivizing performance improvement on these measures among participating hospitals. We believe removing these measures from the Hospital VBP Program would reduce costs and complexity for hospitals to separately track the confidential feedback, preview reports, and publicly reported information on these measures in both the Hospital VBP and HAC Reduction Programs. We further believe retaining these measures in the HAC Reduction Program and removing them from the Hospital VBP Program would best support the holistic approach to the measures used in the three quality payment programs as described above, while continuing to keep patient safety and improvements in patient safety as high priorities. We refer readers to section IV.J.4 b., d., and h. of the preamble of this proposed rule for how the same HAI measures in the HAC Reduction Program will continue to be reported by hospitals via the CDC's NHSN and posted on our *Hospital Compare* website. Therefore, we believe that removing these measures from the Hospital VBP Program, but retaining them in the HAC Reduction Program, strikes an appropriate balance of benefits and costs associated with these measures across payment programs. We also refer readers to section VIII.A.5.b.(2)(b) of the preamble of this proposed rule, where we are proposing to remove these same measures from the Hospital IQR Program.

Therefore, we are proposing to remove the CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measures from the Hospital VBP Program beginning with the FY 2021 program year, with data collection on these measures for purposes of the Hospital VBP Program ending with December 31, 2018 discharges, based on proposed removal Factor 8—because the costs associated with the measures outweigh the benefit of their continued use in the program. We are also proposing to remove the PSI 90 measure from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule based on proposed removal Factor 8—because the costs associated with the measure outweigh the benefit of its continued use in the program.[256] As the PSI 90 measure would not be incorporated into TPS calculations until the FY 2023 program year, we can operationally remove the measure from the program sooner than the HAI measures. We also refer readers to section IV.I.4.a.(2) and b. of the preamble of this proposed rule, where we are proposing to remove the Safety domain from the Hospital VBP Program and to increase the weight of the Clinical Care domain (which we are proposing to rename as the Clinical Outcomes domain) if our proposals to remove all of the current Safety domain measures are adopted, beginning with the FY 2021 program year.

We are inviting public comment on these proposals to remove the five HAI measures and the PSI 90 measure from the Hospital VBP Program, as well as comments on whether the removal of these measures from this program and their retention in the HAC Reduction Program would continue to provide a strong incentive for performance on these patient safety measures.

(3) Proposed Removal of Condition-Specific Payment Measures

We are proposing to remove the following three condition-specific payment measures from the Hospital VBP Program, effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, because the costs associated with the measures outweigh the benefit of their continued use in the program—proposed removal Factor 8:

- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (NQF #2431) (AMI Payment);
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (NQF #2436) (HF Payment); and
- Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579) (PN Payment).

As discussed in section IV.I.2.b. of the preamble of this proposed rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures. We also seek to reduce costs and complexity across the hospital quality programs.

Currently, the Hospital IQR and Hospital VBP Programs both include the Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158) (MSPB)

[256] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256), we finalized the adoption of the PSI 90 measure beginning with the FY 2023 program year. We are proposing to remove this measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measure would not be used in calculating hospitals' TPS for any program year.

measure, as well as the three condition-specific payment measures listed above. We continue to believe the condition-specific payment measures provide important data for patients and hospitals, and we will continue to use these measures in the Hospital IQR Program along with the Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip and/or Total Knee Arthroplasty measure, to provide more granular information to hospitals for reducing costs and resource use while maintaining quality care. However, we believe that continuing to retain the AMI Payment, HF Payment, and PN Payment measures in both the Hospital VBP and Hospital IQR Programs no longer aligns with current CMS and HHS policy priorities for reducing program costs and complexity. We believe the Hospital IQR Program's public reporting of these condition-specific payment measures provide hospitals and patients with sufficient information to make decisions about care and to drive resource use improvement efforts, while removing them from the Hospital VBP Program would reduce the costs and complexity for hospitals to separately track the confidential feedback, preview reports, and publicly reported information on these measures in both programs. We note that the Hospital VBP Program would still retain the MSPB measure, which is an overall hospital efficiency measure required under section 1886(o)(2)(B)(ii) of the Act. We also refer readers to section VIII.A.5.b.(6) of the preamble of this proposed rule, where we are proposing to remove the MSPB measure from the Hospital IQR Program.

Therefore, we are proposing to remove the AMI Payment, HF Payment, and PN Payment measures from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule based on proposed removal Factor 8—because the costs associated with the measures outweigh the benefit of their continued use in the program. As the AMI Payment and HF Payment measures [257] would not be incorporated into TPS calculations until the FY 2021 program year and the PN Payment measure [258] would not be incorporated into TPS calculations until the FY 2022 program year, we can operationally remove these measures from the program sooner than the HAI measures.

We are inviting public comment on this proposal to remove the three condition-specific payment measures from the Hospital VBP Program, as well as comments on whether there are potential reasons to retain these condition-specific payment measures in the program.

d. Summary of Previously Adopted Measures for the FY 2020 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38244), we finalized the following measure set for the Hospital VBP Program for the FY 2020 program year. We note that we are not proposing any changes to this measure set in this proposed rule.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PROGRAM YEAR

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)
	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	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
THA/TKA	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	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 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
PC–01	Elective Delivery	0469

[257] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56987 through 56992), we adopted the AMI Payment and HF Payment measures in the Hospital VBP Program beginning with the FY 2021 program year. We are proposing to remove these measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measures would not be used in calculating hospitals' TPS for any program year.

[258] In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251), we adopted the PN Payment measure in the Hospital VBP Program beginning with the FY 2022 program year. We are proposing to remove this measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, meaning the measure would not be used in calculating hospitals' TPS for any program year.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PROGRAM YEAR—Continued

Measure short name	Domain/measure name	NQF #
	Efficiency and Cost Reduction Domain	
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.
** As discussed in sections IV.I.4.a.(2) and IV.I.2.c.(1) and (2) of the preamble of this proposed rule, respectively, we are proposing to remove the Safety domain and the measures in the Safety domain, beginning with the following program year (FY 2021).

e. Summary of Measures for the FY 2021, FY 2022, and FY 2023 Program Years if Proposals for Removal of Measures are Finalized

For the FY 2021 program year, we are proposing to remove six measures from the Safety domain (PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), as all of the HAI measures will be retained in the HAC Reduction Program, and to remove the Safety domain itself, as there would be no measures remaining in the domain, along with proposing to remove two measures from the Efficiency and Cost Reduction domain (AMI Payment and HF Payment). If these measure removals are finalized as proposed, the Hospital VBP Program measure set for the FY 2021 program year would contain the following measures:

SUMMARY OF MEASURES FOR THE FY 2021 PROGRAM YEAR IF PROPOSED MEASURE REMOVALS ARE FINALIZED *

Measure short name	Domain/measure name	NQF No.
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	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
THA/TKA	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

* As discussed in sections IV.I.2.c.(1) and (2) and IV.I.2.c.(3) of the preamble of this proposed rule, respectively, we are proposing to remove six measures in the Safety domain (PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) beginning with the FY 2021 program year, and two measures in the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year. As discussed in section IV.I.4.a.(2) of the preamble of this proposed rule, we are also proposing to remove the Safety domain itself beginning with the FY 2021 program year. Therefore, we did not include these measures or the Safety domain in this summary table.
** We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

For the FY 2022 and FY 2023 program years, in addition to the eight measures we are proposing to remove for the FY 2021 program year (PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, CDI, AMI Payment, and HF Payment), we are also proposing to remove the PN Payment measure, which would be entering the program beginning with the FY 2022 program year, and the PSI 90 measure, which would be entering the program beginning with the FY 2023 program year. If all of these measure removals are finalized as proposed, the Hospital VBP Program measure set for the FY 2022 and 2023 program years would contain the following measures:

SUMMARY OF MEASURES FOR THE FY 2022 AND FY 2023 PROGRAM YEARS IF PROPOSED MEASURE REMOVALS ARE FINALIZED *

Measure short name	Domain/measure name	NQF No.
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure).	0166 (0228)
	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
THA/TKA	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

* As discussed in sections IV.I.2.c.(1) and (2) and IV.I.2.c.(3) of the preamble of this proposed rule, respectively, we are proposing to remove six measures in the Safety domain (PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) beginning with the FY 2021 program year, and two measures in the Efficiency and Cost Reduction domain (AMI Payment and HF Payment), which would have entered the program beginning with the FY 2021 program year; the PN Payment measure, which would have entered the program beginning with the FY 2022 program year; and the PSI 90 measure, which would have entered the program beginning with the FY 2023 program year. As discussed in section IV.I.4.a.(2) of the preamble of this proposed rule, we are also proposing to remove the Safety domain itself beginning with the FY 2021 program year. Therefore, we did not include these measures or the Safety domain in this summary table.

** We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

3. Accounting for Social Risk Factors in the Hospital VBP Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241 through 38242), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[259] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[260] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38241), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[261] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[262] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: To explore whether

[259] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[260] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[261] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[262] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

4. Scoring Methodology and Data Requirements

a. Proposed Changes to the Hospital VBP Program Domains

(1) Proposed Domain Name Change for the FY 2020 Program Year and Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49553 through 49554), we renamed the Clinical Care—Outcomes subdomain as the Clinical Care domain beginning with the FY 2018 program year. As discussed in the section I.A.2. of the preamble of this proposed rule, we strive to have measures in our programs that can drive improvement in patients' health outcomes. We also strive to align quality measurement and value-based payment programs with other national strategies, such as the Meaningful Measures Initiative. As discussed in section IV.I.2.c. of the preamble of this proposed rule, we believe that one of the primary areas of focus for the Hospital VBP Program should be on measures of clinical outcomes, such as measures of mortality and complications, which address the Meaningful Measures Initiative quality priority of promoting effective treatment. The Clinical Care domain currently contains these types of measures; therefore, to better align the name of the domain with our priority area of focus, we are proposing to change the domain name from Clinical Care to Clinical Outcomes, beginning with the FY 2020 program year. We believe this proposed domain name better captures our goal of driving improvement in health outcomes and focusing on those outcomes that are most meaningful to patients and their providers.

We are inviting public comment on this proposal.

(2) Proposed Removal of the Safety Domain for the FY 2021 Program Year and Subsequent Years

We previously adopted five HAI measures and the PC–01 measure for the Safety domain (82 FR 38242 through 38244). We also previously adopted PSI 90 as a measure in the Safety domain beginning with the FY 2023 program year (82 FR 38251 through 38256). However, as discussed in section IV.I.2.c.(1) and (2) of the preamble of this proposed rule, above, we are proposing to remove the PC–01 measure and the five HAI measures from the Hospital VBP Program beginning with the FY 2021 program year and to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule, as the PSI 90 measure and all five of the HAI measures will be retained in the HAC Reduction Program. We are not proposing any new measures for the Safety domain in this proposed rule. In addition, as discussed in section IV.I.2.c. of the preamble of this proposed rule, by taking a holistic approach to evaluating the appropriateness of the measures used in the three hospital value-based purchasing programs—the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs—we believe the HAC Reduction Program is the primary part of the quality payment framework that should focus on the safety aspect of care quality for the inpatient hospital setting (Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce the costs of duplicative measures and program complexity.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50056) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49546), we noted that hospital acquired condition measures comprise some of the most critical patient safety areas, therefore justifying the use of the measures in more than one program. However, we have also stated that we will monitor the HAC Reduction and Hospital VBP Programs and analyze the impact of our measures selection, including any unintended consequences with having a measure in more than one program, and will revise the measure set in one or both programs if needed (79 FR 50056). We have continued to receive stakeholder feedback expressing concern about overlapping measures amongst different payment programs, such as the Hospital VBP and HAC Reduction Programs. For the Hospital VBP Program, specifically, we believe removing the measures in the Safety domain and retaining them in the HAC Reduction Program directly addresses the concerns expressed by stakeholders about the costs to hospitals participating in these programs so that the costs of participation do not outweigh the benefits of improving beneficiary care.

In this proposed rule, we are proposing to remove the Safety domain from the Hospital VBP Program, beginning with the FY 2021 program year, because there would no longer be any measures in that domain if our measure removal proposals are finalized. We acknowledge that by removing the Safety domain and its

measures from the Hospital VBP Program, the overall effect would be to decrease the total percent of hospital payment at risk that is based on performance on these measures (by no longer tying performance on them to Hospital VBP Program reimbursement), and that it might reduce the current incentive for hospitals to perform as well on them. However, we believe hospitals will still be sufficiently incentivized to perform well on the measures even if they are only in one value-based purchasing program, and we intend to monitor the effects of this proposal, if finalized, as the patient safety measures would be maintained in the HAC Reduction Program, validated, and publicly reported on the *Hospital Compare* website.

We also refer readers to section IV.I.4.b.(2) of the preamble of this proposed rule, where we discuss how we considered keeping the Safety domain and the current domain weighting of 25 percent weight for each of the four domains with proportionate reweighting if a hospital has sufficient data on only three domains, which would include retaining in the Hospital VBP Program one or more of the measures in the Safety domain (such as measures which are also used in the HAC Reduction Program). However, based on the considerations discussed above, we decided to propose removal of the Safety domain measures and the Safety domain from the Hospital VBP Program. If our proposals to remove the Safety domain measures (PC–01, the five HAI measures, and PSI 90) are adopted, there would be no measures left in the Safety domain beginning with the FY 2021 program year.

Therefore, we are proposing to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year.

We are inviting public comment on this proposal and whether we should keep the Safety domain along with one or more of its measures.

b. Proposed Domain Weighting With Increased Weight to Clinical Outcomes and Alternatives Considered for the FY 2021 Program Year and Subsequent Years

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. 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 (79 FR 50084 through 50085).

As discussed above, we are proposing to remove the Hospital VBP Program Safety domain beginning with the FY 2021 program year in connection with our proposal to remove all of the measures previously adopted for the Safety domain. We are also proposing to remove the three condition-specific payment measures (AMI Payment, HF Payment, and PN Payment) effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. If these proposals are adopted, there would be only three domains remaining in the Hospital VBP Program, beginning with the FY 2021 program year—Clinical Outcomes (proposed name change; currently referred to as the Clinical Care domain), Person and Community Engagement, and Efficiency and Cost Reduction. The Clinical Outcomes domain would have five measures of mortality and complications for the FY 2021 program year and 6 measures beginning with the FY 2022 program year, the Person and Community Engagement domain would have the HCAHPS survey with its eight dimensions of patient experience, and the Efficiency and Cost Reduction domain would include only the MSPB measure. To account for these changes, we assessed the weighting of scores on the three remaining domains in constituting each hospital's TPS. Specifically, we considered: (1) Weighting the Clinical Outcomes domain at 50 percent of a hospital's TPS, and to weight the Person and Community Engagement and Efficiency and Cost Reduction at 25 percent each; and (2) weighting all three domains equally, each as one-third (⅓) of a hospital's TPS. Because there would be only three domains if our proposals to remove the Safety domain and all of the Safety domain measures are adopted, we are not proposing any changes to the requirement that a hospital must receive domain scores on at least three domains to receive a TPS. Historically, when the Hospital VBP Program had three domains, scores in all three were required to receive a TPS (76 FR 74534; 76 FR 74544). We also discuss in this section that we considered keeping the current domain weighting (25 percent for each of the four domains—Safety, Clinical Outcomes (proposed name change), Person and Community Engagement, and Efficiency and Cost Reduction—with proportionate reweighting if a hospital has sufficient data on only three domains), which would require keeping at least one or more of the measures in the Safety domain and the Safety domain itself.

(1) Proposed Domain Weighting With Increased Weight to Clinical Outcomes

For the reasons discussed below, in this proposed rule, we are proposing to weight the domains as follows beginning with the FY 2021 program year:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS

Domain	Weight (percent)
Clinical Outcomes *	50
Person and Community Engagement	25
Efficiency and Cost Reduction	25

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

We believe this proposed domain weighting best aligns with our emphasis on clinical outcomes, which address the Meaningful Measures Initiative quality priority of promoting effective treatment, and provides a greater weight for the domain with the greatest number of measures (Clinical Outcomes), while providing appropriate weighting to the domains that focus on patient experience and cost reduction commensurate with their continued importance. In proposing to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of hospitals' TPSs, we took into account that the Clinical Outcomes domain will include five outcome measures for the FY 2021 program year (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN (updated cohort), and THA/TKA) and six outcome measures for the FY 2022 program year (MORT–30–CABG, MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN (updated cohort), and THA/TKA), while the Person and Community Engagement domain includes the HCAHPS survey measure, and the Efficiency and Cost Reduction domain would include only one measure (MSPB) if our proposals to remove the condition-specific payment measures, discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, above, are adopted.

Under this proposed domain weighting, each measure in the Clinical Outcomes domain (measures of mortality and complications) would

comprise 10 percent of each hospital's TPS for the FY 2021 program year and 8.33 percent for the FY 2022 program year and subsequent years, if a hospital meets the case minimum for each measure in the domain, and no more than 25 percent for each measure if a hospital can only meet the minimum two measure scores for the Clinical Outcomes domain. The MSPB measure would continue to be weighted at 25 percent, if our proposals to remove the condition specific payment measures are adopted; and each of the eight HCAHPS dimensions would continue to be weighted at 3.125 percent for a total of 25 percent for the Person and Community Engagement domain. We believe the proposed domain weighting better balances the contributing weights of each individual measure that would be retained in the Hospital VBP Program compared to the alternative weighting we considered of equal weights (one-third (⅓) for each domain), as discussed in more detail below.

We also believe the proposal to increase the weight of the Clinical Outcomes domain would help address concerns expressed by the Government Accountability Office (GAO) in a June 2017 report.[263] In the report, GAO observed that high scores in the Efficiency and Cost Reduction domain resulted in positive payment adjustments for some hospitals that had composite quality scores below the median (the GAO assessed each hospital's composite quality score as its TPS minus its weighted Efficiency and Cost Reduction domain score). GAO also expressed concern that proportionate reweighting of the Efficiency and Cost Reduction domain (for example, from 25 percent to one-third (⅓) of a hospital's TPS in FY 2016), due to a missing domain score for another domain, amplified the contribution of the Efficiency and Cost Reduction domain to the TPS. GAO recommended that CMS take action to avoid disproportionate impact of the Efficiency and Cost Reduction domain on the TPS, and to change the proportionate reweighting policy so it does not facilitate positive payment adjustments for hospitals with lower quality scores. Other stakeholders and researchers have expressed similar concerns.[264]

Using actual FY 2018 program data,[265] we analyzed the estimated potential impacts to hospital TPSs and payment adjustment. Based on this analysis, we estimate that with the proposed domain weighting, approximately 200 hospitals with composite quality scores below the median composite quality score for all Hospital VBP Program-eligible hospitals would no longer receive a positive payment adjustment mainly driven by their high performance on the Efficiency and Cost Reduction domain. This represents an approximate 50 percent reduction in the percent of hospitals receiving positive payment adjustments that have composite quality scores below the median (from 21 percent of hospitals receiving payment adjustments to 11 percent). We refer readers to the table in the section IV.I.4.b.(3) below summarizing the results of this analysis.

In further analyzing the potential impacts of the proposed domain weighting on hospitals' TPSs using actual FY 2018 program data, our analysis showed that, on average, hospitals with large bed size, hospitals in urban areas, teaching hospitals, and safety net status hospitals,[266] which have historically received lower overall TPSs on average (generally due to lower average performance on the Efficiency and Cost Reduction and Patient and Community Engagement domains), moved closer to the average TPS under the proposed domain weighting (generally due to their higher average performance on the Clinical Outcomes domain). With average scores for these types of hospitals moving closer to the average TPS for all hospitals, this would increase their TPSs, on average, and thereby increase their chances for a positive payment adjustment.

On average, hospitals with small bed size, rural hospitals, and non-teaching hospitals, which were historically high scorers on average (generally due to higher average performance on the Efficiency and Cost Reduction and Patient and Community Engagement domains), also moved closer to the average TPS under the proposed domain weighting (generally due to lower average performance on the Clinical Outcomes domain). With average scores for these types of hospitals also moving closer to the average TPS for all hospitals, this would decrease their TPSs, on average, and thereby decrease their chances for a positive payment adjustment. This would also be consistent with our analysis discussed above that the proposed domain weighting would better address GAO's recommendations for the Hospital VBP Program by reducing the percent of hospitals receiving positive payment adjustments that have composite quality scores below the median.

Our analysis also simulated that removing the Safety domain and increasing the weight of the Clinical Outcomes domain would have decreased the slope of the linear exchange function from 2.89 (actual FY 2018) to 2.78 (estimated using actual FY 2018 program data) and would have decreased the percent of hospitals receiving a positive payment adjustment from 57 percent to 45 percent. We believe this is mainly due to hospitals with greater total MS–DRGs payments (such as larger hospitals that generally have higher average performance on the Clinical Outcomes domain) earning higher TPSs relative to hospitals with smaller total MS–DRGs payments in this estimated budget-neutral program. We refer readers to the tables in section IV.I.4.b.(3) below summarizing the results of these analyses.

(2) Alternatives Considered

As an alternative, we also considered weighting each of the three domains equally, meaning that each domain (Clinical Outcomes, Person and Community Engagement, and Efficiency and Cost Reduction) would be weighted as one-third (⅓) of a hospital's TPS, which is similar to the proportionate reweighting policy when a hospital is missing one domain score due to insufficient cases to score enough measures for the domain. Our analysis showed that, on average, hospitals with small bed size, rural hospitals, non-teaching hospitals, and non-safety net status hospitals would earn TPSs relatively closer to or better than historic levels of performance, particularly with increased weighting of the Patient and Community Engagement and Efficiency and Cost Reduction domains from 25 percent each to one-third (⅓) each, domains in which these

[263] *Hospital Value-Based Purchasing: CMS Should Take Steps to Ensure Lower Quality Hospitals Do Not Quality for Bonuses: Report to Congressional Committees.* (GAO Publication No. GAO–17–551) Retrieved from U.S. Government Accountability Office: Available at: *https://www.gao.gov/assets/690/685586.pdf.*

[264] For example, Ryan AM, Krinsky S, Maurer KA, Dimick JB. Changes in Hospital Quality Associated with Hospital Value-Based Purchasing. N Engl J Med. 2017 June 15;376(24):2358–2366.

[265] Only eligible hospitals were included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the State of Maryland) were removed from this analysis.

[266] For purposes of this analysis, ''safety net'' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

types of hospitals historically perform better than average compared to large bed size, hospitals in urban areas, teaching hospitals, and safety net status hospitals.[267] In addition, our analysis showed that equally weighting the domains does not address the GAO's concern of positive payment adjustments for hospitals with composite quality scores below the median. Based on our analyses, we estimate that approximately 20 percent of hospitals with composite quality scores below the median composite quality score for all Hospital VBP Program-eligible hospitals would receive a positive payment adjustment mainly driven by their high performance on the Efficiency and Cost Reduction domain, if we weighted the domains equally. This is approximately double the number of hospitals that we estimate would receive a positive payment adjustment with composite quality scores below the median as compared to our proposed domain weighting of increasing the Clinical Outcomes domain to 50 percent and keeping the Patient and Community Engagement and Efficiency and Cost Reduction domains at 25 percent each. We refer readers to the tables in section IV.I.4.b.(3) of the preamble of this proposed rule summarizing the results of these analyses.

We also considered keeping the Safety domain and the current domain weighting (25 percent weight for each of the four domains with proportionate reweighting if a hospital has sufficient data on only three domains), which would include retaining in the Hospital VBP Program one or more of the measures in the Safety domain (such as measures which are also used in the HAC Reduction Program). As discussed in section IV.I.2.c. of the preamble of this proposed rule, we continue to consider patient safety and reducing HAIs as high priorities, which is why the PSI 90 and five HAI measures being proposed for removal from the Hospital VBP Program will continue to be used in the HAC Reduction Program.

As discussed earlier, we believe the more holistic quality payment program strategy we seek to undertake will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity. For the Hospital VBP Program, specifically, we believe removing the measures in the Safety domain and retaining them in the HAC Reduction Program directly addresses the concerns expressed by provider stakeholders about the costs to hospitals participating in these programs so that the costs of participation do not outweigh the benefits of improving beneficiary care.

(3) Analysis

Our priority is to adopt a domain weighting policy that appropriately reflects hospital performance under the Hospital VBP Program, aligns with CMS policy goals, including the more holistic quality payment program strategy for hospitals discussed above, and continues to incentivize quality improvement. As noted above, to understand the potential impacts of the proposed domain weighting on hospitals' TPSs, we conducted analyses using FY 2018 program data that estimated the potential impacts of our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS and an alternative weighting policy we considered of equal weights whereby each domain would constitute one-third (⅓) of a hospital's TPS. The table below provides an overview of the estimated impact on hospitals' TPS by certain hospital characteristics and as they would compare to actual FY 2018 TPSs, which include scoring on four domains, including the Safety domain, and applying proportionate reweighting if a hospital has sufficient data on only three domains.

COMPARISON OF ESTIMATED AVERAGE TPSS AND UNWEIGHTED DOMAIN SCORES *

Hospital characteristic	Actual FY 2018 average clinical care domain score	Actual FY 2018 average person and community engagement domain score	Actual FY 2018 average efficiency and cost reduction domain score	Actual FY 2018 average TPS (4 domains) +	Proposed increased weighting of clinical care domain: estimated average TPS	Alternative weighting: estimated average TPS
All Hospitals **	43.2	33.5	18.8	37.4	34.6	31.8
Bed Size:						
1–99	33.4	46.0	35.7	44.6	37.2	38.4
100–199	42.2	34.5	21.0	39.2	35.0	32.6
200–299	44.5	27.9	12.9	34.4	32.4	28.4
300–399	48.2	27.3	10.0	33.3	33.4	28.5
400+	50.9	26.9	7.6	31.9	34.1	28.5
Geographic Location:						
Urban	46.8	30.7	13.7	35.7	34.5	30.4
Rural	33.7	40.5	31.7	41.9	34.9	35.3
Safety Net Status: ***						
Non-Safety Net	42.7	35.4	19.0	37.9	34.9	32.4
Safety Net	45.1	25.7	18.1	35.6	33.5	29.6
Teaching Status:						
Non-Teaching	39.9	36.7	22.9	39.4	34.9	33.2
Teaching	48.7	27.9	11.8	34.1	34.3	29.5

* Analysis based on FY 2018 Hospital VBP Program data.

** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

[267] For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS final rule impact file, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

The table below provides a summary of the estimated impacts on average TPSs and payment adjustments for all hospitals,[268] including as they would compare to actual FY 2018 program results under current domain weighting policies.

Summary of estimated impacts on average TPS and payment adjustments using FY 2018 program data	Actual (4 domains) +	Proposed increased weight for clinical outcomes (3 domains)	Equal weighting alternative (3 domains)
Total number of hospitals with a payment adjustment	2,808	2,701	2,701
Number of hospitals receiving a positive payment adjustment (percent)	1,597 (57%)	1,209 (45%)	1,337 (50%)
Average positive payment adjustment percentage	0.60%	0.58%	0.70%
Estimated average positive payment adjustment	$128,161	$233,620	$204,038
Number of hospitals receiving a negative payment adjustment (percent)	1,211 (43%)	1,492 (55%)	1,364 (50%)
Average negative payment adjustment percentage	−0.41%	−0.60%	−0.57%
Estimated average negative payment adjustment	$169,011	$189,307	$200,000
Number of hospitals receiving a positive payment adjustment with a composite quality score * below the median (percent)	341 (21%)	134 (11%)	266 (20%)
Average TPS	37.4	34.6	31.8
Lowest TPS receiving a positive payment adjustment	34.6	35.9	30.9
Slope of the linear exchange function	2.8908851882	2.7849297316	3.2405954322

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

* ''Composite quality score'' is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score.

The estimated total number of hospitals with a payment adjustment is lower under the proposed domain weighting and equal weighting alternative considered (2,701), compared to the current four domain policy (2,808), because under the proposed domain weighting and equal weighting alternative, scores would be required on all three domains (Clinical Care (proposed Clinical Outcomes), Person and Community Engagement, and Efficiency and Cost Reduction) to receive a TPS and hence, a payment adjustment, whereas under the current scoring policy, if a hospital has sufficient data on any three of the four domains it can receive a TPS and payment adjustment. For example, under the current scoring policy, if a hospital does not have sufficient data for a score on the Clinical Care (Clinical Outcomes) domain, but receives a score on the other three domains (Safety, Person and Community Engagement, and Efficiency and Cost Reduction), the hospital could have its domain scores proportionately reweighted and receive a TPS and payment adjustment, whereas under the proposed domain weighting and equal weighting alternative considered (which do not include the Safety domain and retain the requirement for at least three domain scores to receive a TPS), a hospital that does not have sufficient data for a score on the Clinical Care (Clinical Outcomes) domain would not receive a TPS or payment adjustment.

We also refer readers to section I.H.6.b. of Appendix A of this proposed rule for a detailed discussion regarding the estimated impacts of the proposed domain weighting and equal weighting alternative on hospital percentage payment adjustments.

(4) Summary

Based on our analyses and all of the other considerations discussed above, we believe our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS best aligns with the goal of the Hospital VBP Program to make value-based incentive payment adjustments based on hospitals' performance on quality and cost, as well as emphasizes the Meaningful Measures Initiative's focus on high impact areas that are meaningful to patients and providers. As discussed in sections IV.I.4.a.(2), IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we believe removing the Safety domain and its measures from the Hospital VBP Program supports the holistic approach to the measures collectively used in the three quality payment programs. Patient safety and reducing HAIs continues to be a high priority for us, which is why we believe retaining the PSI 90 and HAI measures in the HAC Reduction Program is important and will continue to incentivize quality improvement in this area, directly addressing the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. We believe removing the same measures from the Hospital VBP Program would also reduce program costs and complexity for hospitals, and directly address their concerns about high program costs and their feedback to reduce duplicative measures between programs.

Because we are proposing to remove the Safety domain and its measures from the Hospital VBP Program, we considered the two options for weighting the three remaining domains. Increasing the weight of the Clinical Outcomes domain from 25 percent to 50 percent of each hospital's TPS emphasizes our priority and focus on improving patients' health outcomes, without decreasing the weight of the

[268] Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

Efficiency and Cost Reduction or Person and Communities Engagement domains. By contrast, equally weighting each of the three domains at one-third (⅓) of each hospital's TPS would result in the MSPB measure and the HCAHPS survey measure together accounting for two-thirds (⅔) of each hospital's TPS.

If our proposal to remove the Safety domain beginning with the FY 2021 program year is adopted, we are proposing to weight the three remaining domains as follows: Clinical Outcomes domain—50 percent; Person and Community Engagement domain—25 percent; and Efficiency and Cost Reduction domain—25 percent—beginning with the FY 2021 program year.

We are inviting comment on our proposal and alternatives considered.

c. Minimum Numbers of Measures for Hospital VBP Program Domains for the FY 2021 Program Year and Subsequent Years

Based on previously finalized policies (82 FR 38266), for a hospital to receive a TPS for the FY 2021 program year and subsequent years:

- 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 (currently referred to as the Clinical Care domain).
- A hospital must receive a minimum of one measure score within the Efficiency and Cost Reduction domain.

As discussed in section IV.I.4.a.(2) of the preamble of this proposed rule, we are proposing to remove the Safety domain from the Hospital VBP Program beginning with the FY 2021 program year. We note that if our proposal to remove the condition-specific payment measures from the Hospital VBP Program is finalized as proposed, a hospital's Efficiency and Cost Reduction domain scores would be based solely on its MSPB measure score.

In this proposed rule, we are not proposing any changes to this policy.

d. Minimum Numbers of Cases for Hospital VBP Program Measures for the FY 2021 Program Year and Subsequent Years

(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 53609); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267).

(2) Clinical Care Domain (Proposed Clinical Outcomes Domain)

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a minimum number of 25 cases for the MORT–30–AMI, MORT–30–HF, and MORT–30–PN measures. We adopted the same 25-case minimum for the MORT–30–COPD measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570), and for the MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA measures in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011).

In this proposed rule, we are not proposing any changes to these policies.

(3) Person and Community Engagement Domain

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we adopted a minimum number of 100 completed HCAHPS surveys for a hospital to receive a score on the HCAHPS measure.

In this proposed rule, we are not proposing any changes to this policy.

(4) Efficiency and Cost Reduction Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53609 through 53610), we adopted a minimum of 25 cases in order to receive a score for the MSPB measure. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086), we retained the same MSPB measure case minimum for the FY 2016 program year and subsequent years. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38267), we adopted a policy that hospitals must report a minimum number of 25 cases per measure in order to receive a measure score for the condition-specific payment measures (namely, the AMI Payment, HF Payment, and PN Payment measures), for the FY 2021 program year, FY 2022 program year, and subsequent years.

In this proposed rule, we are not proposing any changes to these policies for the MSPB measure; however, as discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove the three condition-specific payment measures (AMI Payment, HF Payment, and PN Payment) from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

(5) Summary of Previously Adopted Minimum Numbers of Cases for the FY 2021 Program Year and Subsequent Years

The previously adopted minimum numbers of cases for these measures are set forth in the table below.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2021 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.

PREVIOUSLY ADOPTED MINIMUM CASE NUMBER REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Measure short name	Minimum number of 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.
THA/TKA	Hospitals must report a minimum number of 25 cases.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

*We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

5. 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 2019, FY 2020, FY 2021, and FY 2022 program years. In the same 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) 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 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.

In this proposed rule, we are not proposing any changes to these policies.

c. Efficiency and Cost Reduction Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 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, 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 (81 FR 56998).

In this proposed rule, we are not proposing any changes to these policies.

d. Clinical Care Domain (Proposed Clinical Outcomes Domain)

For the FY 2020 and FY 2021 program years, we adopted a 36-month baseline period and 36-month performance period for measures in the Clinical Outcomes domain (currently referred to as the Clinical Care domain) (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).[269] In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a 36-month performance period and 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, THA/TKA, and MORT–30–CABG measures. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also adopted a 22-month performance period for the MORT–30–PN (updated cohort) measure and a 36-month baseline period for the FY 2021 program year. In the same final rule, we adopted a 34-month performance period and 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 36-month baseline period for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort), and THA/TKA 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, five years prior to the applicable fiscal program year, to June 30, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from July 1, ten years prior to the applicable fiscal program year, to June 30, seven years prior to the applicable fiscal program year. For the THA/TKA measure, the performance period runs for 36 months from April 1, five years prior to the applicable fiscal program year, to March 31, two years prior to the applicable fiscal program year, and the baseline period runs for 36 months from April 1, ten years prior to the applicable fiscal program year, to March 31, seven years prior to the applicable fiscal program year.

In this proposed rule, we are not proposing any changes to the length of these performance or baseline periods.

e. Safety Domain

In the FY 2017 IPPS/LTCH PPS final rule, we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the PSI 90 measure—that runs on the calendar year two 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

[269] The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563).

subsequent program years (81 FR 57000). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38242 through 38244, 38251 through 38256), we removed the former PSI 90 measure beginning with the FY 2019 program year, and adopted the Patient Safety and Adverse Events (Composite) (PSI 90) measure beginning with the FY 2023 program year, along with baseline and performance periods for the measure (80 FR 38258 through 38259).

As discussed in sections IV.I.4.a.(2), IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we are proposing to remove the Safety domain and remove the PC–01 and the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia) beginning with the FY 2021 program year, and to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

f. Summary of Previously Adopted Baseline and Performance Periods for the FY 2020 Through FY 2024 Program Years

The tables below summarize the baseline and performance periods that we have previously adopted.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; SAFETY; AND EFFICIENCY AND COST REDUCTION DOMAINS

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.
Clinical Outcomes: *		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN) • THA/TKA.	• July 1, 2010–June 30, 2013 • July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018. • July 1, 2015–June 30, 2018.
Safety: **		
• PC–01 and NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.
Efficiency and Cost Reduction:		
• MSPB	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in sections IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we are proposing to remove PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures beginning with the FY 2021 program year.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * AND EFFICIENCY AND COST REDUCTION DOMAINS **

Domain	Baseline period	Performance Period
Person and Community Engagement:		
• HCAHPS	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
Clinical Outcomes: *		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD).	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2019.
• THA/TKA	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.
Efficiency and Cost Reduction: ***		
• MSPB	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we are proposing to remove PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures beginning with the FY 2021 program year, which would leave no measures in the Safety domain. As a result, the Safety domain and the previously finalized performance and baseline periods for those six measures are not included in this table.

*** As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove AMI Payment and HF Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance and baseline periods for those measures are not included in this table.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * AND EFFICIENCY AND COST REDUCTION DOMAINS **

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.
Clinical Outcomes: *		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG).	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• September 1, 2017–June 30, 2020.
• THA/TKA	• April 1, 2012–March 31, 2015	• April 1, 2017–March 31, 2020.
Efficiency and Cost Reduction: ***		

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * AND EFFICIENCY AND COST REDUCTION DOMAINS **—Continued

Domain	Baseline period	Performance period
• MSPB	• January 1, 2018–December 31, 2018	• January 1, 2020–December 31, 2020.

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we are proposing to remove PC–01, CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia measures beginning with the FY 2021 program year, which would leave no measures in the Safety domain. As a result, the Safety domain and the previously finalized performance and baseline periods for those six measures are not included in this table.

*** As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance and baseline periods for these three measures are not included in this table.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2023 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * AND EFFICIENCY AND COST REDUCTION DOMAINS **

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).	• July 1, 2013–June 30, 2016	• July 1, 2018–June 30, 2021.
• THA/TKA	• April 1, 2013–March 31, 2016	• April 1, 2018–March 31, 2021.
Efficiency and Cost Reduction: ***		
• MSPB	• January 1, 2019–December 31, 2019	• January 1, 2021–December 31, 2021.

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in sections IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we are proposing to remove PC–01 and the NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) beginning with the FY 2021 program year and we are proposing to remove the PSI 90 measure effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. If finalized these proposals would leave no measures in the Safety domain. As a result, the Safety Domain and these seven measures are not included in this table.

*** As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance and baseline periods for these three measures are not included in this table.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2024 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT; CLINICAL OUTCOMES; * AND EFFICIENCY AND COST REDUCTION DOMAINS **

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).	• July 1, 2014–June 30, 2017	• July 1, 2019–June 30, 2022.
• THA/TKA	• April 1, 2014–March 31, 2017	• April 1, 2019–March 31, 2022.
Efficiency and Cost Reduction: ***		
• MSPB	• January 1, 2020–December 31, 2020	• January 1, 2022–December 31, 2022.

* We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

** As discussed in section IV.I.2.c.(1) and (2) of the preamble of this proposed rule, we are proposing to remove PC–01 and the NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) beginning with the FY 2021 program year and we are proposing to remove the PSI 90 effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. If finalized these proposals would leave no measures in the Safety domain. As a result, the Safety Domain and these seven measures are not included in this table.

*** As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance and baseline periods for these three measures are not included in this table.

6. Previously Adopted and Proposed 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, 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 50080 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

b. Previously Adopted and Proposed Performance Standards for the FY 2021 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38263), we summarized the previously adopted performance standards for the FY 2021 program year for the Clinical Care domain (proposed Clinical Outcome domain) measures (MORT–30–HF, MORT–30–AMI, MORT–30–COPD, THA/TKA, and MORT–30–PN (updated cohort)) 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. The previously adopted performance standards for the measures in the Clinical Care (proposed Clinical Outcome domain) and Efficiency and Cost Reduction domains for the FY 2021 program year are set out in the tables below.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR: CLINICAL OUTCOMES ∧ AND EFFICIENCY AND COST REDUCTION DOMAINS #

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain ∧*		
MORT–30–AMI	0.860355	0.879714
MORT–30–HF	0.883803	0.906144
MORT–30–PN (updated cohort)	0.836122	0.870506
MORT–30–COPD	0.923253	0.938664
THA/TKA**	0.031157	0.022418
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.

∧ We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove the AMI Payment and HF Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance standards for those measures are not included in this table.

* We note that the mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

** Lower values represent better performance.

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, thus 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.

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), we are proposing to adopt performance standards for the FY 2021 program year for the Person and Community Engagement domain. We note that the numerical values for the proposed performance standards displayed in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2019 IPPS/LTCH PPS final rule.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN ±

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	55.75	79.05	87.27
Communication with Doctors	56.94	80.11	88.17
Responsiveness of Hospital Staff	40.36	65.41	80.39
Communication about Medicines	20.95	63.64	74.40
Hospital Cleanliness & Quietness	42.76	65.63	79.74
Discharge Information	68.87	87.49	92.18
Care Transition	6.65	51.68	63.24

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN ±—Continued

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Overall Rating of Hospital	36.42	71.76	85.64

±The performance standards displayed in this table were calculated using one quarter (Q4) CY 2016 data and three quarters (Q1, Q2, and Q3) CY 2017 data. We will update this table's performance standards using four quarters of CY 2017 data in the final rule.

We are inviting public comments on these proposed performance standards for the FY 2021 program year.

c. Previously Adopted Performance Standards for Certain Measures for the FY 2022 Program Year

We have adopted certain measures for the Clinical Care (proposed Clinical Outcome domain) and Efficiency and Cost Reduction domains 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 2017 IPPS/LTCH PPS final rule (81 FR 57009), we adopted performance standards for the FY 2022 program year for the Clinical Care domain (proposed Clinical Outcome domain) measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN (updated cohort), MORT–30–COPD, and MORT–30–CABG) 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. The previously adopted performance standards for these measures are set out in the table below.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain ^*		
MORT–30–AMI	0.861793	0.881305
MORT–30–HF	0.879869	0.903608
MORT–30–PN (updated cohort)	0.836122	0.870506
MORT–30–COPD	0.920058	0.936962
MORT–30–CABG †	0.968210	0.979000
THA/TKA **	0.029833	0.021493
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.

^We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.

†After publication of the FY 2017 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for this measure. Specifically, the Achievement Threshold and Benchmark values, while accurate, were presented in the wrong categories. We corrected this issue in the FY 2018 IPPS/LTCH PPS final rule, and the correct performance standards are displayed here in the table above.

*The mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.

**Lower values represent better performance.

#As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove the AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance standards for those three measures are not included in this table.

d. Previously Adopted Performance Standards for Certain Measures for the FY 2023 Program Year

We have adopted certain measures for the Clinical Care (proposed Clinical Outcome domain) and Efficiency and Cost Reduction domains 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 2018 IPPS/LTCH PPS final rule (82 FR 38264 through 38265), we adopted the following performance standards for the FY 2023 program year for the Clinical Care domain (proposed Clinical Outcome domain) measures (THA/TKA, MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, and MORT–30–CABG) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38264), we stated our intent to propose performance standards for the PSI 90 measure in this year's rulemaking. However, as discussed in section IV.I.2.c.(2) of the preamble of this proposed rule, we are proposing to remove the PSI 90 measure from the Hospital VBP Program effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. For this reason, we are not including proposed performance standards for this measure in this proposed rule. We note that the performance standards for the MSPB measure is based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. The previously adopted performance standards for these measures are set out in the table below.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR THE FY 2023 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
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
THA/TKA**	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.

∧ We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.
* The mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.
** Lower values represent better performance.
# As discussed in section IV.I.2.c.(3) of the preamble of this proposed rule, we are proposing to remove the AMI Payment, HF Payment, and PN Payment measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. As a result, the previously finalized performance standards for those three measures are not included in this table.

e. Proposed Performance Standards for Certain Measures for the FY 2024 Program Year

We have adopted certain measures for the Clinical Care (proposed Clinical Outcome domain) and Efficiency and Cost Reduction domains for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. We are proposing the following performance standards for the FY 2024 program year for the Clinical Care domain (proposed Clinical Outcome domain) and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure is based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time. These newly proposed performance standards for these measures are set out in the table below.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2024 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
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
THA/TKA**	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.

∧ We are proposing, in section IV.I.4.a.(1) of the preamble of this proposed rule, to change the name of this domain from the Clinical Care domain to the Clinical Outcomes domain beginning with the FY 2020 program year.
* The mortality measures in the Hospital VBP Program use survival rates rather than mortality rates; as a result, higher values indicate better performance on these measures.
** Lower values represent better performance.

We are inviting public comments on these proposed performance standards for the FY 2024 program year.

J. Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the preamble of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. For a detailed discussion of the statutory basis of the HAC Reduction Program, we refer readers to section V.I.2. of the preamble of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709). For a further description of our previously finalized policies for the HAC Reduction Program, we refer readers to 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) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278). These policies describe the general framework for implementation of the HAC Reduction Program, 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) 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; and (6) limitation of administrative and judicial review.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

By publicly reporting quality data, we strive to put patients first by ensuring they, along with their clinicians, are empowered to make decisions about their own healthcare using information aligned with meaningful quality measures. The HAC Reduction Program, together with the Hospital VBP Program and the Hospital Readmissions Reduction Program, represents a key component of the way that we bring quality measurement, transparency, and improvement together with value-based purchasing programs to the inpatient care setting. We have undertaken efforts to review the existing HAC Reduction Program measure set in the context of these other programs, to identify how to reduce costs and complexity across programs while continuing to incentivize improvement in the quality and value of care provided to patients. To that end, we have begun reviewing our programs' measures in accordance with the Meaningful Measures Initiative we described in section I.A.2. of the preamble of this proposed rule.

As part of this review, we have taken a holistic approach to evaluating the appropriateness of the HAC Reduction Program's current measures in the context of the measures used in two other IPPS value-based purchasing programs (that is, the Hospital VBP Program and the Hospital Readmissions Reduction Program), as well as in the Hospital IQR Program. We view the three value-based purchasing programs together as a collective set of hospital value-based purchasing programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs. The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending per Beneficiary measure (which addresses the Meaningful Measures Initiative priority of making care affordable). We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

As previously stated, the HAC Reduction Program focuses on making care safer by reducing harm caused in the delivery of care. Measures in the HAC Reduction Program, generally represent ''never events'' [270] and often, if not always, assess preventable conditions. By including these measures in the Program, we seek to encourage hospitals to address the serious harm caused by these adverse events and to reduce them. Therefore, after thoughtful review, we have determined that the Patient Safety and Adverse Events Composite (PSI 90) and the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures (NHSN HAI measures) are most appropriately included as part of the HAC Reduction Program, and we are proposing to remove these measures from the Hospital IQR and VBP Programs. We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance while streamlining the measure sets.

The HAC Reduction Program has historically relied on Hospital IQR Program processes for administrative support; we therefore are proposing HAC Reduction Program-specific healthcare-associated infection measure data collection and validation requirements, and scoring associated with data completeness, timeliness, and accuracy. Contingent upon the Hospital IQR Program finalizing its proposal to remove NHSN HAI measures from its program (section VIII.A.5.b.(2)(b) of the preamble of this proposed rule), the HAC Reduction Program is proposing to formally adopt analogous processes and independently manage these administrative processes to receive CDC NHSN data and begin validation seamlessly with January 1, 2019 infectious events. We note that if the Hospital IQR Program does not finalize its proposal to remove NHSN HAI measures from its program, then the HAC Reduction Program would subsequently not finalize its proposals to manage the associated administrative processes.

In this proposed rule, for the HAC Reduction Program, we are proposing to: (1) Establish administrative policies for the HAC Reduction Program to collect, validate, and publicly report quality measure data independently instead of conducting these activities through the Hospital IQR Program; (2) adjust the scoring methodology by removing domains and assigning equal weighting to each measure for which a hospital has a measure score in order to improve fairness across hospital types in the Program; (3) establish the data collection period for the FY 2021 Program Year; and (4) solicit

[270] ''The term ''Never Event'' was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. The NQF initially defined 27 such events in 2002. The list has been revised since then, most recently in 2011, and now consists of 29 events grouped into 7 categories: surgical, product or device, patient protection, care management, environmental, radiologic, and criminal.'' Never Events, Available at: *https://psnet.ahrq.gov/primers/primer/3/never-events.*

stakeholder feedback regarding the potential future inclusion of additional measures, including eCQMs.

2. Accounting for Social Risk Factors in the HAC Reduction Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38273 through 38276), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[271] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[272] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38274), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[273] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[274] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. Previously-Adopted Measures for FY 2019 and Subsequent Years

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57013 through 57020), we finalized the Patient Safety and Adverse Events Composite (PSI 90)[275] measure for use in the FY 2018 program and subsequent years for Domain 1. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) measures for Domain 2 for use in the FY 2015 program and subsequent years. Currently, the Program utilizes five NHSN measures: CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia. These previously finalized measures, with their full measure names, are shown in the table below.

[271] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[272] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[273] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[274] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

[275] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS quality programs.

HAC REDUCTION PROGRAM MEASURES FOR FY 2019

Short name	Measure name	NQF No.
Domain 1:		
CMS PSI 90	Patient Safety and Adverse Events Composite	0531
Domain 2:		
CAUTI	NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	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	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

4. Administrative Policies for the HAC Reduction Program for FY 2019 and Subsequent Years

a. Measure Specifications

As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) for the Hospital IQR Program and subsequently finalized for the HAC Reduction Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we will use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program and to use rulemaking to adopt substantive updates to measures. As with the Hospital IQR Program, we will determine what constitutes a substantive versus nonsubstantive change on a case-by-case basis. As we have stated in past rulemaking (79 FR 50100), examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe nonsubstantive changes may also include nonsubstantive updates to NQF-endorsed measures based upon changes to the measures' underlying clinical guidelines.

We will continue to use rulemaking to adopt substantive updates, and a subregulatory process to make nonsubstantive updates, to measures we have adopted for the HAC Reduction Program. As stated in past rules (78 FR 50776), examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus nonsubstantive would apply to all measures in the HAC Reduction Program.

We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process, which is available through its website at: *http://www.qualityforum.org/projectlisting.aspx*. We believe this policy adequately balances our need to incorporate updates to HAC Reduction Program measures in the most expeditious manner possible while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

Technical specifications for the CMS PSI 90 in Domain 1 can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228695355425*. Technical specifications for the NHSN HAI measures in Domain 2 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.

b. Proposed Data Collection Beginning CY 2019

We are proposing to adopt data collection processes for the HAC Reduction Program to receive CDC NHSN data beginning with January 1, 2019 infection events to correspond with the Hospital IQR Program's calendar year reporting period and maintain the HAC Reduction Program's annual performance period start date. All reporting requirements, including quarterly frequency, CDC collection system, and deadlines would not change from current Hospital IQR Program requirements to aid continued hospital reporting through clear and consistent requirements. This proposed start date aligns with the effective date of the Hospital IQR Program's proposed removal of these measures beginning with CY 2019 reporting period/FY 2021 payment determination as discussed in section VIII.A.5.b.(2)(b) of the preamble of this rule and should allow for a seamless transition.

The HAC Reduction Program identifies the worst-performing quartile of hospitals by calculating a Total HAC Score derived from the CMS PSI 90 and NHSN HAI measures, which require that we collect claims-based and chart-abstracted measures data, respectively. No additional collection mechanisms are required for the CMS PSI 90 measure because it is a claims-based measure calculated using data submitted to CMS by hospitals for Medicare payment, and therefore imposes no additional administrative or reporting requirements on participating hospitals. For the NHSN HAI measures, if the Hospital IQR Program finalizes its proposal to remove them from its program, we are proposing to adopt the HAI data collection process established in the Hospital IQR Program. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50190), where we finalized the CDC NHSN as the mechanism to submit data on the NHSN HAI measures to the Hospital IQR Program, and to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723), where the HAC Reduction Program stated that it would obtain HAI measure results that hospitals submitted to the CDC NHSN for the Hospital IQR Program. Hospitals would continue to submit data through the CDC NHSN portal located by selecting ''NHSN Reporting'' after

signing in at: *https://sams.cdc.gov*, and the HAC Reduction Program would receive the NHSN data directly from the CDC instead of through the Hospital IQR Program as an intermediary.

We also are proposing to adopt the Hospital IQR Program's exception policy to reporting and data submission requirements for the CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI measures. As noted in FY 2013 IPPS/LTCH PPS final rule (77 FR 53539) and in FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822) for the Hospital IQR Program and in FY 2015 IPPS/LTCH PPS final rule (79 FR 50096) for the HAC Reduction Program, CMS acknowledges that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting and that some hospitals may perform so few procedures requiring surveillance under the Colon and Abdominal Hysterectomy SSI measure that the data may not be meaningful for public reporting nor sufficiently reliable to be utilized for a program year. If a hospital does not have adequate locations or procedures, it should submit the Measure Exception Form to the HAC Reduction Program beginning on January 1, 2019. The IPPS Quality Reporting Programs Measure Exception Form is located using the link located on the QualityNet website under the Hospitals – Inpatient > Hospital Inpatient Quality Reporting Program tab at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021*. As has been the case under the Hospital IQR Program, hospitals seeking an exception would submit this form at least annually to be considered.

Beginning in FY 2019, the HAC Reduction Program would provide the same NHSN HAI measures quarterly reports that stakeholders are accustomed to under the Hospital IQR Program. However, some hospitals that elected not to participate in the Hospital IQR Program may be unfamiliar with them. These reports, provided via the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*, provide hospitals with their facility's quarterly measure data as well as facility-, State- and national-level results for the measures. To access their reports, hospitals must register for a QualityNet Secure Portal Account. We anticipate the transition to occur without interruption, with the only change to stakeholders being that they would receive reports from both the HAC Reduction Program and the Hospital IQR Program for the respective measures adopted in each program.

c. Review and Correction of Claims Data Used in the HAC Reduction Program for FY 2019 and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727), we detailed the process for the review and correction of claims-based data, and we are not proposing any changes. We calculate the measure in Domain 1 using a static snapshot (data extract) taken after the 90-day period following the last date of discharge used in the applicable period. We create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2018, we would create the data extract on September 30, 2018, and use those data to calculate the claims based measures for that applicable period.

Hospitals are not able to submit corrections to the underlying claims snapshot used for the Domain 1 measure calculations after the extract date, and are not be able to add claims to this data set. Therefore, hospitals are encouraged to ensure that their claims are accurate prior to the snapshot date. We consider hospitals' claims data to be complete for purposes of calculating the Domain 1 for the HAC Reduction Program after the 90-day period following the last date of discharge used in the applicable period.

For more information, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727). We reiterate that under this process, hospitals retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies, but the administrative claims data used to calculate the Domain 1 measure and the resulting Domain Score reflect the state of the claims at the time of extraction from CMS' CWF.

We are not proposing any change to our current administrative policy regarding the submission, review, and correction of claims data.

d. Review and Correction of Chart-Abstracted NHSN HAI Data Used in the HAC Reduction Program for FY 2019 and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726), we stated that the HAC Reduction Program would use the same process as the Hospital IQR Program for hospitals to submit, review, and correct data for chart-abstracted NHSN HAI measures. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), we clarified that hospitals had an opportunity to submit, review, and correct any of the chart-abstracted information for the full 4 ½ months after the end of the reporting quarter. We also noted that for the purposes of fulfilling CMS quality measurement reporting requirements, each facility's data must be entered into NHSN no later than 4 ½ months after the end of the reporting quarter.

For a detailed description of the process, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50726) where we explained that hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule not only to allow them sufficient time to identify errors and resubmit data before the quarterly submission deadline, but also to identify opportunities for continued improvement. Users may view and make corrections to the data that they submit starting immediately following submission. The data are populated into reports that are updated immediately with all data that have been submitted successfully. We believe that 4½ months is sufficient time for hospitals to submit, review, and make corrections to their HAI data. We also balance the correction needs of hospitals with the need to publicly report and refresh measure information on *Hospital Compare* in a timely manner. Historically, CMS has generally refreshed HAI data on a quarterly basis on *Hospital Compare* in the Hospital IQR Program.

We wish to clarify that this HAI review and correction process is intended to permit hospitals review of measure performance and data submission feedback. Hospitals can use the NHSN system during the quarterly data submission period to identify any errors made in the reporting of a patient's specific ''infection event,'' the denominator (that is, overall admissions data), and other NHSN protocol data used to calculate measure results before the quarterly submission deadline. The HAI review and correction process is different than and occurs prior to the annual Scoring Calculations Review and Correction Process, which is intended to ensure the accurate calculation of measure scoring used for payment, and is discussed in section IV.J.4.g. of the preamble of this proposed rule.

We are not proposing any changes to our current administrative policy regarding the submission, review, and correction of chart-abstracted HAI data.

e. Proposed Changes to Existing Validation Processes

As discussed in above in section IV.J.1. of the preamble of this proposed rule, we are proposing to adopt processes to validate the NHSN HAI measure data used in the HAC Reduction Program if the Hospital IQR Program finalizes its proposals to remove NHSN HAI measures from its program. While the HAC Reduction Program cannot adopt the Hospital IQR Program's process as is for various reasons as discussed below, we intend for the HAC Reduction Program's processes to reflect, to the greatest extent possible, the current processes previously established the Hospital IQR Program. 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), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403) for detailed information on the Hospital IQR Program's validation processes.

Currently, CMS estimates accuracy for the hospital-reported data submitted to the clinical warehouse and data submitted to NHSN as reproduced by a trained abstractor using a standardized NHSN HAI measure abstraction protocol created by CDC and CMS and posted on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?cid=%201228776288808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page*. We are proposing to adopt the validation processes into the HAC Reduction Program as previously established by the Hospital IQR Program (with some exceptions as discussed below) in this section as follows: Section IV.J.4.e.(1) of the preamble of this proposed rule (proposed measures subject to validation); section IV.J.4.e.(2) of the preamble of this proposed rule (proposed provider selection); section (IV.J.4.e.(3) of the preamble of this proposed rule (proposed targeting criteria); section IV.J.4.e.(4) of the preamble of this proposed rule (proposed calculation of the confidence period); section IV.J.4.e.(5) of the preamble of this proposed rule (proposed educational review process); section IV.J.4.e.(6) of the preamble of this proposed rule (proposed application of validation penalty); and section IV.J.4.e.(7) of the preamble of this proposed rule (proposed validation period).

(1) Proposed Measures Subject to Validation

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50828 through 50832) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50264 through 50265), the Hospital IQR Program identified the following chart-abstracted NHSN HAI measures submitted via NHSN as being subject to validation: CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia.

In this proposed rule, we are proposing that chart-abstracted NHSN HAI measures submitted via NHSN would be subject to validation in the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022. As stated in section IV.J.3. of the preamble of this proposed rule, above, and as finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), the HAC Reduction Program currently includes five NHSN HAI measures: CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia.

We are inviting public comment on our proposal.

(2) Proposed Provider Selection

For chart-abstracted data validation in the Hospital IQR Program, CMS currently performs a random and targeted selection of participating hospitals on an annual basis, as initially set out in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50833 through 50834). For example, in December of 2017, CMS randomly selected 400 hospitals for validation for the FY 2020 payment determination. In April/May of 2018, an additional targeted provider sample of up to 200 hospitals are selected (78 FR 50833 through 50834). We intend to mirror these policies for the HAC Reduction Program, and thus, we are proposing annual random selection of 400 hospitals and the annual targeted selection of 200 hospitals using the targeting criteria proposed below in section IV.J.4.e.(3) of the preamble of this proposed rule.

Unlike the Hospital IQR Program, which includes only hospitals with active Notices of Participation (77 FR 53536), we intend to include all subsection (d) hospitals in these proposed validation procedures, since all subsection (d) hospitals are subject to the HAC Reduction Program. Therefore, for the HAC Reduction Program, we are proposing to include all subsection (d) hospitals in the provider sample for validation beginning with the Q3 2019 discharges for FY 2022. We believe this would be better representative of hospitals impacted by the Program. We note that for the FY 2018 HAC Reduction Program, which uses CY 2015 and 2016 NHSN HAI data, 44 hospitals were subject to the HAC Reduction Program, but chose not to participate in the Hospital IQR Program. These hospitals would be included in the validation process.

We are inviting public comment on our proposal.

(3) Proposed Targeting Criteria

As stated above, the Hospital IQR Program currently performs a random and targeted selection of hospitals for validation on an annual basis (78 FR 50833 through 50834). In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229), the Hospital IQR finalized that the targeted selection will include all hospitals that failed validation the previous year. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553), the Hospital IQR Program finalized additional criteria for selecting targeted hospitals: Any hospital with abnormal or conflicting data patterns; any hospital with rapidly changing data patterns; 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; and any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent. In the FY 2014 IPPS/LTCH PPS final rule, the Hospital IQR Program expanded its targeting criteria to include 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. We intend to propose similar policies for the HAC Reduction Program.

Therefore, we are proposing the following targeting criteria for the HAC Reduction Program beginning with the Q3 2019 discharges for FY 2022:

- Any hospital that failed validation the previous year;
- Any hospital that submits data to NHSN after the HAC Reduction Program data submission deadline has passed;
- Any hospital that not been randomly selected for validation in the past 3 years;
- Any hospital that passed validation in the previous year, but had a two-

tailed confidence interval that included 75 percent; [276] and

- 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.

We are inviting public comment on our proposals.

(4) Proposed Calculation of the Confidence Interval

The Hospital IQR Program scores hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol (77 FR 53548). As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53550 through 53551), the Hospital IQR Program uses the upper bound of a two-tailed 90 percent confidence interval around the combined clinical process of care and HAI scores to determine if a hospital passes or fails validation; if this number is greater than or equal to 75 percent, then the hospital passes validation.

We believe that a similar computation of the confidence interval is appropriate for the HAC Reduction Program, but that it include only the NHSN HAI measures and not the clinical process of care measures, which are not a part of the Program's measure set. Therefore, we are proposing that for the HAC Reduction Program beginning in FY 2022: (1) We would score hospitals based on an agreement rate between hospital-reported infections compared to events identified as infections by a trained CMS abstractor using a standardized protocol; (2) we would compute a confidence interval; (3) if the upper bound of this confidence interval is 75 percent or higher, the hospital would pass the HAC Reduction Program validation requirement; and (4) if the upper bound is below 75 percent, the hospital would fail the HAC Reduction Program validation requirement.

We are inviting public comment on our proposals.

(5) Proposed Educational Review Process

Under the Hospital IQR Program, within 30 days of validation results being posted on the QualityNet Secure Portal at: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*, if a hospital has a question or needs further clarification on a particular outcome, the hospital may request an educational review (82 FR 38402 through 38403). Furthermore, if an educational review that is requested for any of the first three quarters of validation yields incorrect CMS validation results for chart-abstracted measures, the corrected quarterly score will be used to compute the final confidence interval (82 FR 38402 through 38403).

We plan to have similar procedures under the HAC Reduction Program. Therefore, for the HAC Reduction Program beginning with the Q3 2019 data validation, we are proposing to have an educational review process, such that hospitals selected for validation would have a 30-day period following the receipt of quarterly validation results to seek educational review. During this 30-day period, hospitals may review, seek clarification, and potentially identify a CMS validation error. In addition, like the Hospital IQR Program, we are proposing that if an educational review is timely requested for any of the first three quarters and the review yields an incorrect CMS validation result, the corrected quarterly score would be used to compute the final confidence interval. Unlike the Hospital IQR Program educational review process (82 FR 38402), we are also proposing that if an educational review is timely requested and an error is identified in the 4th quarter of review, we would use the corrected quarterly score to compute the final confidence interval.

We are inviting public comment on our proposals.

(6) Proposed Application of Validation Penalty

Currently, under the Hospital IQR Program, we randomly assign half of the hospitals selected for validation to submit CLABSI and CAUTI Validation Templates and the other half of hospitals to submit MRSA and CDI Validation Templates (78 FR 50826 through 50834). CMS selects up to four candidate NHSN HAI cases per hospital from each of the assigned Validation Templates (79 FR 50263 through 50265). CMS also selects up to two candidate Colon and Abdominal Hysterectomy SSI cases from Medicare claims data for patients who had colon surgeries or abdominal hysterectomies that appear suspicious of infection (78 FR 50826 through 50834). The Hospital IQR Program applies a full payment reduction if a hospital fails to meet any part of the validation process (75 FR 50219 through 50220; 81 FR 57180).

For the HAC Reduction Program, if a hospital does not meet the overall validation requirement, we are proposing to penalize hospitals that fail validation by assigning the maximum Winsorized z-score only for the set of measures CMS validated. For example, if a hospital was in the half selected to submit CLABSI and CAUTI Validation Templates but failed the validation, we are proposing that hospital receive the maximum Winsorized z-score for CLABSI, CAUTI, and Colon and Abdominal Hysterectomy SSI. Although it would better align with the Hospital IQR Program's current ''all or nothing'' approach (75 FR 50219 through 50220; 81 FR 57180) to penalize hospitals by assigning the maximum Winsorized z-scores for the entire domain, we believe that our chosen approach would be fairer to hospitals and would lessen the likelihood of their automatically ranking in the worst-performing quartile based on validation results. Furthermore, we believe our proposed approach better aligns with the current HAC Reduction Program policy of assigning the maximum Winsorized z-score if hospitals do not submit data to NHSN for a given NHSN HAI measure (81 FR 57013).

(7) Proposed Validation Period

The Hospital IQR Program currently uses a calendar year reporting period for NHSN HAI measures (76 FR 51644). For example, the FY 2020 measure reporting quarters include Q1 2018, Q2 2018, Q3 2018, and Q4 2018. Under the Hospital IQR Program, FY 2020 data validation consists of the following quarters: Q3 2017, Q4 2017, Q1 2018, and Q2 2018, the Hospital IQR Program schedule is available on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?cid=%201228776288808&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page*. Currently, the HAC Reduction Program utilizes NHSN HAI data from two calendar years to calculate measure results. For example, the FY 2021 measure reporting quarters include Q1 2018 through Q4 2019.

When determining the proposed validation period for the HAC Reduction Program, we considered the performance and validation cycles currently in place under the Hospital IQR Program, and we considered key public reporting dates for the HAC Reduction Program. HAC Reduction Program scores must be calculated in time for hospital specific reports (HSRs) to be issued annually, usually in July, and the 30-day Scoring Calculations Review and Correction period of the HSRs serves as the preview period for *Hospital Compare.* Then, HAC Reduction Program data published on *Hospital Compare* is refreshed annually as soon as feasible following the review period.

[276] We will devise a two-tailed confidence interval formula using only NHSN HAI measures for the HAC Reduction Program. This will be posted to the QualityNet website.

After consideration, we are proposing that the HAC Reduction Program's performance period would remain 2 calendar years and that the validation period would include the four middle quarters in the HAC Reduction Program performance period (that is, third quarter through second quarter). This approach aligns with current the HAC Reduction Program performance period, it also aligns with current NHSN HAI validation quarters, and because we would continue to collect eight quarters of measure data, we anticipate no impact on the reliability of NHSN HAI results.

Because our validation sample of hospitals is selected annually and because of the time needed to build the required infrastructure, we believe the earliest opportunity to seamlessly begin this work under the HAC Reduction Program is Q3 2019. Therefore, we are proposing that the HAC Reduction Program would begin validation of NHSN HAI measures data with July 2019 infection event data. The proposed commencement of validation, along with key validation dates, is shown in the table below.

PROPOSED VALIDATION PERIOD FOR THE HAC REDUCTION PROGRAM

[* Dates are subject to change]

Discharge quarters by fiscal year (FY)	Current NHSN HAI submission deadline *	Current NHSN HAI validation templates *	Estimated CDAC record request	Estimated date records due to CDAC	Estimated validation completion
FY 2022:					
Q1 2019	08/15/2019				
Q2 2019	11/15/2019				
Q3 2019∧	02/15/2020	02/01/2020	02/28/2020	03/30/2020	06/15/2020
Q4 2019∧	05/15/2020	05/01/2020	05/30/2020	06/29/2020	09/15/2020
Q1 2020∧	08/15/2020	08/01/2020	08/30/2020	09/29/2020	12/15/2020
Q2 2020∧	11/15/2020	11/01/2020	11/29/2020	12/29/2020	03/15/2021
Q3 2020	02/15/2021				
Q4 2020	05/15/2021				
FY 2023:					
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
Q3 2021	02/15/2022				
Q4 2021	05/15/2022				

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.

To maintain symmetry with the current Hospital IQR Program validation schedule as set forth on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1140537256076*, we are proposing that for hospitals selected for validation, the NHSN HAI validation templates would be due before the HAC Reduction Program NHSN HAI data submission deadlines. To the greatest extent possible, we are proposing to keep the processes the same as they are currently implemented in the Hospital IQR Program. Because these deadlines would function in the same manner as the current policy under the Hospital IQR Program, we expect that most providers are familiar with this process. For more information, we refer readers to the Chart-Abstracted Data Validation Resources information available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1140537256076&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page.*

We are inviting public comment regarding our validation proposals.

f. Proposed Data Accuracy and Completeness Acknowledgement (DACA)

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for DACA requirements previously adopted by the Hospital IQR Program. We are proposing that if the Hospital IQR Program finalizes its proposal to remove NHSN HAI measures from its program, then the HAC Reduction Program would adopt this same process. Hospitals would have to electronically acknowledge the data submitted are accurate and complete to the best of their knowledge. Hospitals would be required to complete and sign the DACA on an annual basis via the QualityNet Secure Portal: *https://cportal.qualitynet.org/QNet/pgm_select.jsp*. The submission period for signing and completing the DACA is April 1 through May 15, with respect to the time period of January 1 through December 31 of the preceding year. The initial HAC Reduction Program proposed annual DACA signing and completing period would be April 1 through May 15, 2020 for calendar year 2019 data.

We are inviting public comment regarding our proposal to adopt DACA requirements.

g. Scoring Calculations Review and Correction Period

Although we are not proposing any changes to the review and correction procedures for FY 2019, we intend to rename the annual 30-day review and correction period to the ''Scoring Calculations Review and Correction Period.'' The purpose of the annual 30-day review and corrections period is to allow hospitals to review the calculation of their HAC Reduction Program scores, and the new name would more clearly convey both the intent and limitation. The naming convention would further distinguish this period from earlier opportunities during which hospitals can review and correct their underlying data.

The HAC Reduction Program will continue to provide annual confidential hospital-specific reports and discharge level information used in the calculation of their Total HAC Scores

via the QualityNet Secure Portal. As noted in section IV.J.4.b. of the preamble of this proposed rule regarding quarterly reports, hospitals must also register at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115992011* for a QualityNet Secure Portal account in order to access their annual hospital-specific reports.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50725 through 50728), hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review their HAC Reduction Program scores, submit questions about the calculation of their results, and request corrections for their HAC Reduction Program scores prior to public reporting. Hospitals may use the 30-day Scoring Calculations Review and Correction Period to request corrections to the following information prior to public reporting:

- CMS PSI 90 measure score
- CMS PSI 90 measure result and Winsorized measure result
- Domain 1 score
- CLABSI measure score
- CAUTI measure score
- Colon and Abdominal Hysterectomy SSI measure score
- MRSA Bacteremia measure score
- CDI measure score
- Domain 2 score
- Total HAC Score

As we clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), this 30-day period is not an opportunity for hospitals to submit additional corrections related to the underlying claims data for the CMS PSI 90, or to add new claims to the data extract used to calculate the results. Hospitals have an opportunity to review and correct claims data used in the HAC Reduction Program as described in section IV.J.4.c. of the preamble of this proposed rule, and detailed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50726 through 50727).

As we also clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38270 through 38271), this 30-day period is not an opportunity for hospitals to submit additional corrections related to the underlying NHSN HAI data used to calculate the scores, including: Reported number of NSHN HAIs; Standardized Infection Ratios (SIRs); or reported central-line days, urinary catheter days, surgical procedures performed, or patient days. Hospitals would have an opportunity to review and correct chart-abstracted NHSN HAI data used in the HAC Reduction Program as described in section IV.J.4.d. of the preamble of this proposed rule.

h. Proposed Public Reporting of Hospital-Specific Data Beginning FY 2019

(1) Proposed Public Reporting of Hospital-Specific Data Beginning FY 2019

Section 1886(p)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding HAC rates of each subsection (d) hospital'' under the HAC Reduction Program. Section 1886(p)(6)(B) of the Act also requires the Secretary to ''ensure that an applicable hospital has the opportunity to review, and submit corrections for, the HAC information to be made public for each hospital.'' Section 1886(p)(6)(C) of the Act requires the Secretary to post the HAC information for each applicable hospital on the *Hospital Compare* website in an easily understood format.

Generally, data collected during the first quarter of a calendar year are publicly reported annually. As finalized in FY 2014 IPPS/LTCH PPS final rule (78 FR 50725), we will make the following information public on the *Hospital Compare* website: (1) Hospital scores with respect to each measure; (2) each hospital's domain-specific score; and (3) the hospital's Total HAC Score. If the Hospital IQR Program finalizes its proposal to remove the CMS PSI 90 from the Program, the CMS PSI 90 individual indicator measure results (that is, the child measures) would be reported under the HAC Reduction Program. The CMS PSI 90 measure is reported on the *Hospital Compare* web pages; however, the child measures are reported in the downloadable database on *Hospital Compare.* Similarly, we believe the NHSN HAI measures represent important quality data consumers of healthcare can use to make informed decisions. Therefore, we intend to continue making NHSN HAI data available to the public on a quarterly basis. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38324), our current policy has been to report data under the Hospital IQR Program as soon as it is feasible on CMS websites such as the *Hospital Compare* website, *http://www.medicare.gov/hospitalcompare*, after a 30-day preview period. We are proposing to make data available in the same form and manner as currently displayed under the Hospital IQR Program.

We intend to maintain as much consistency as possible in how the measures are currently reported on *Hospital Compare,* including how they are displayed and the frequency of reporting.

(2) Clarification of Location of Publicly-Reported HAC Reduction Program Information

Section 1886(p)(6)(C) of the Act, as codified at 42 CFR 412.172(f), requires that HAC information is posted on the *Hospital Compare* website in an easily understandable format. *Hospital Compare* is the official website for the publication of the required HAC Reduction Program data, and the location where the HAC Reduction Program will continue to post data. We believe the above approach complies with the Act and provides hospitals and the public sufficient access to information.

i. Limitation on Administrative and Judicial Review

Section 1886(p)(7) of the Act, as codified at 42 CFR 412.172(g), provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for any of the following:

- The criteria describing an applicable hospital in paragraph 1886(p)(2)(A) of the Act;
- The specification of hospital acquired conditions under paragraph 1886(p)(3) of the Act;
- The specification of the applicable period under paragraph 1886(p)(4) of the Act;
- The provision of reports to applicable hospitals under paragraph 1886(p)(5) of the Act; and
- The information made available to the public under paragraph 1886(p)(6) of the Act.

For additional information, we refer readers to FY 2014 IPPS/LTCH PPS final rule (78 FR 50729) and FY 2015 IPPS/LTCH PPS final rule (79 FR 50100).

5. Proposed Changes to the HAC Reduction Program Scoring Methodology

We regularly examine the HAC Reduction Program's scoring methodology for opportunities for improvement. This year, we examined several alternative scoring options that would allow the scoring methodology to continue to fairly assess all hospitals.

a. Current Methodology

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57022 through 57025), we adopted a Winsorized z-score scoring methodology for FY 2018 in which we rank hospitals by calculating a Total HAC Score based on hospitals' performance on two domains: patient

safety (Domain 1) and NHSN HAIs (Domain 2). Domain 1 includes the CMS PSI 90 measure. Domain 2 includes the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI,[277] MRSA Bacteremia, and CDI measures. Under the current scoring methodology, hospitals' Total HAC Scores are calculated as a weighted average of Domain 1 (15 percent) and Domain 2 (85 percent). Hospitals with a measure score for at least one Domain 2 measure receive a Domain 2 score. Hospitals with 3 or more discharges for at least one component indicator for the CMS PSI 90 receive a Domain 1 score. The first table below illustrates the weight CMS applies to each measure for the roughly 99 percent of non-Maryland hospitals with a Domain 1 score and the second table below illustrates the weight CMS applies to each measure for the one percent of non-Maryland hospitals without a Domain 1 score.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITH A DOMAIN 1 SCORE IN FY 2018

[N = 3,147]

Number of Domain 2 measures with measure scores	Number (percent) of hospitals in FY 2018 [a]	Weight applied to:	
		CMS PSI 90	Each Domain 2 measure
0	188 (5.9%)	100.0	N/A
1	288 (9.1%)	15.0	85.0
2	218 (6.9%)	15.0	42.5
3	196 (6.2%)	15.0	28.3
4	251 (7.9%)	15.0	21.3
5	2,006 (63.0%)	15.0	17.0

[a] The denominator for percentage calculations is all non-Maryland hospitals with a FY 2018 Total HAC Score.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITHOUT A DOMAIN 1 SCORE IN FY 2018

[N = 36]

Number of Domain 2 measures with measure scores	Number (percent) of hospitals in FY 2018 [a]	Weight applied to:	
		CMS PSI 90	Each Domain 2 measure
1	8 (0.3%)	N/A	100.0
2	7 (0.2%)	N/A	50.0
3	2 (0.1%)	N/A	33.3
4	2 (0.1%)	N/A	25.0
5	16 (0.5%)	N/A	20.0

[a] The denominator for percentage calculations is all non-Maryland hospitals with a FY 2018 Total HAC Score.

As shown in the first table above, under the currently methodology, the weight applied to the CMS PSI 90 and each Domain 2 measure is almost the same (15.0 and 17.0 percent, respectively) for hospitals with measure scores for all six program measures. However, for hospitals with between one and four Domain 2 measures, the weight applied to the CMS PSI 90 is lower (and in some cases much lower) than the weight applied to each Domain 2 measure. For hospitals with a measure score for only one or two Domain 2 measures (that is, low-volume hospitals in particular), a disproportionately large weight is applied to each Domain 2 measure. Several stakeholders voiced concerns about the disproportionately large weight applied to the one or two Domain 2 measures for which low-volume hospitals have a measure score. As seen in the tables above; under the currently methodology, the weighting for the Domain 2 measures is dependent on the number of measures with data for those hospitals without a Domain 1 score.

In this proposed rule, we are discussing two alternative scoring methodologies for calculating hospitals' Total HAC Scores. Our preferred approach, the Equal Measure Weights policy, involves removing domains and applying an equal weight to each measure for which a hospital has a measure score in Total HAC Score calculations. However, we are seeking public comment on an additional approach: applying a different weight to each domain depending on the number of measures for which a hospital has a measure score (Variable Domain Weights).

b. Equal Measure Weights

In this proposed rule, our preferred approach is the Equal Measure Weights Policy. We would remove domains from the HAC Reduction Program and simply assign equal weight to each measure for which a hospital has a measure score. We would calculate each hospital's Total HAC Score as the equally weighted average of the hospital's measure scores. The table below displays the weights applied to each measure under this approach. All other aspects of the HAC Reduction Program scoring methodology would remain the same, including the calculation of measure scores as Winsorized z-scores, the determination of the 75th percentile Total HAC Score, and the determination of the worst-performing quartile.

[277] Colon and Abdominal Hysterectomy SSI is reported as one score under the HAC Reduction Program.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF MEASURES WITH MEASURE SCORE FOR HOSPITALS WITH AND WITHOUT A CMS PSI 90 SCORE UNDER EQUAL MEASURE WEIGHTS APPROACH

Number of NHSN HAI measures with measure score	Weight applied to:	
	CMS PSI 90	Each NHSN HAI measure
0	100.0	N/A
1	50.0	50.0
2	33.3	33.3
3	25.0	25.0
4	20.0	20.0
5	16.7	16.7
Any number	N/A	100.0 (equally divided among each NHSN HAI measure).

As shown in the table above, by applying an equal weight to each measure for all hospitals, the Equal Measure Weights approach addresses stakeholders' concerns about the disproportionately large weight applied to Domain 2 measures for certain hospitals under the current scoring methodology.

c. Alternative Methodology Considered: Variable Domain Weights

We also analyzed a Variable Domain Weights approach. Under this approach, the weights applied to Domain 1 and Domain 2 depend upon the number of measure scores a hospital has in each domain. The table below displays the weights applied to each domain under this approach.

WEIGHT APPLIED TO EACH MEASURE BY NUMBER OF DOMAIN 2 MEASURES WITH MEASURE SCORES FOR HOSPITALS WITH AND WITHOUT A DOMAIN 1 SCORE UNDER VARIABLE DOMAIN WEIGHTS APPROACH

Number of Domain 2 measures with measure score	Weight applied to:		
	Domain 1 (CMS PSI 90)	Domain 2	Each Domain 2 measure
0	100.0	N/A	N/A
1	40.0	60.0	60.0
2	30.0	70.0	35.0
3	20.0	80.0	26.7
4	15.0	85.0	21.3
5	15.0	85.0	17.0
Any number	N/A	100.0	Equally divided.

As shown in the table above, under the Variable Domain Weights approach, the difference in the weight applied to the CMS PSI 90 and each Domain 2 measure is smaller than the difference under the current scoring methodology for hospitals that have a Domain 1 score (the first table under the Equal Measure Weights approach discussion, above).

d. Analysis

Our priority is to adopt a policy that improves the scoring methodology and increases fairness for all hospitals. Both proposed approaches address stakeholders' concerns about the disproportionate weight applied to Domain 2 measures for low-volume hospitals. We simulated results under each scoring approach using FY 2018 HAC Reduction Program data. We compared the percentage of hospitals in the worst-performing quartile in FY 2018 to the percentage that would be in the worst-performing quartile under each scoring approach. The table below provides a high-level overview of the impact of these approaches on several key groups of hospitals.

ESTIMATED IMPACT OF SCORING APPROACHES ON PERCENTAGE OF HOSPITALS IN WORST-PERFORMING QUARTILE BY HOSPITAL GROUP

Hospital group [a]	Equal measure weights	Variable domain weights
Teaching hospitals: 100 or more residents (N = 248)	2.4%	1.6%
Safety-net [b] (N = 644)	0.6%	0.8%
Urban hospitals: 400 or more beds (N = 360)	2.2%	1.1%
Hospitals with 100 or fewer beds (N = 1,169)	−1.8%	−0.9%
Hospitals with a measure score for:		
Zero Domain 2 measures (N = 188)	0.0%	0.0%
One Domain 2 measure (N = 269)	−4.2%	−1.9%
Two Domain 2 measures (N = 225)	−0.8%	−0.4%
Three Domain 2 measures (N = 198)	−2.5%	−2.5%
Four Domain 2 measures (N = 253)	−0.4%	0.4%
Five Domain 2 measures (N = 2,022)	1.0%	0.5%

[a] The number of hospitals in the given hospital group for FY 2018 is specified in parenthesis in this column (for example, N = 248).
[b] Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent.

As shown in the table above, the Equal Measure Weights approach generally has a larger impact than the Variable Domain Weights approach. Under the Equal Measure Weights Approach, as compared to the current methodology using FY2018 HAC Reduction Program data, the percentage of hospitals in the worst-performing quartile decreases by 1.8 percent for small hospitals (that is, 100 or fewer beds), 4.2 percent for hospitals with one Domain 2 measure, 0.8 percent for hospitals with two Domain 2 measures, while it increases by 2.2 percent for large urban hospitals (that is, 400 or more beds) and 2.4 percent for large teaching hospitals (that is, 100 or more residents). The Variable Domain Weights approach changes the percentage of hospitals in the worst-performing quartile by less than two percent for these groups of hospitals.

We prefer the Equal Measure Weights approach because it reduces the percentage of low-volume hospitals in the worst-performing quartile in the simplest manner to hospitals, while not greatly increasing the potential costs on other hospital groups. In addition, should we add measures or remove measures from the program in the future, we would not need to modify the weighting scheme under the Equal Measure Weights approach, unlike the current scoring methodology or the Variable Domain Weights approach.

Finally, the Equal Measure Weights policy aligns with the intent of the original program design to apply a similar weight to each measure. That is, we applied a weight of 35 percent to Domain 1 and 65 percent to Domain 2 in FY 2015, so that the weight applied to each measure would be roughly the same for hospitals with measure scores for all measures. When we added Colon and Abdominal Hysterectomy SSI to Domain 2 in FY 2016 and CDI and MRSA Bacteremia in FY 2017, we increased the weight of Domain 2 to 75 percent and 85 percent, respectively, so that the weight applied to each measure would be nearly the same for hospitals with measure scores for all measures. However, the static domain weights we applied for these program years led to a substantially lower weight being applied to the CMS PSI 90 compared with Domain 2 measures for hospitals with only one or two Domain 2 measures. After assessing the results of our analysis and these additional considerations, we are proposing to adopt the Equal Measure Weights Policy starting in FY 2020.

We also recognize that under this proposal the NHSN HAI portfolio of up to five measures would continue to be weighted much more highly than the CMS PSI 90 for the vast majority of hospitals with more than one NHSN HAI data meeting minimum precision criteria (MPC) of 1.0. For example, hospitals reporting five NHSN HAI measures meeting the MPC of 1.0 and CMS PSI 90 would be weighted as 83.33 percent using the equal weighting proposal for the set of NHSN HAI measures and 16.67 percent for the CMS PSI 90. Hospitals reporting fewer NHSN HAIs meeting the MPC of 1.0 would receive lower total HAI weighting to account for the reduced number of NHSN HAI measures.

This proposal is intended to address the impact of disproportionate weighting at the measure level for the subset of hospitals with relatively few NHSN HAI measures. Under the current weighting methodology, hospitals reporting on a single NHSN HAI measure receive 85 percent measure level weight for that one measure.

We are inviting public comment on our proposed preferred change to the HAC Reduction Program scoring methodology and the alternative considered.

6. Proposed Applicable Period for FY 2021

Consistent with the definition specified at § 412.170, we are proposing to adopt the applicable period for the FY 2021 HAC Reduction Program for the CMS PSI 90 as the 24-month period from July 1, 2017 through June 30, 2019, and the applicable period for NHSN HAI measures as the 24-month period from January 1, 2018 through December 31, 2019.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38271), we finalized a return to a 24-month data collection period for the calculation of HAC Reduction Program measure results. As we stated then, we believe that using 24 months of data for the CMS PSI 90 and the NHSN HAI measures balances the Program's needs against the burden imposed on hospitals' data-collection processes, and allows for sufficient time to process the data for each measure and calculate the measure results.

We are inviting public comment on this proposal.

7. Request for Comments on Additional Measures for Potential Future Adoption

As we did in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19986 through 19990), and as part of our ongoing efforts to evaluate and strengthen the HAC Reduction Program, we seek stakeholder feedback on the adoption of additional Program measures.

We welcome public comment and suggestions for additional HAC Reduction Program measures, specifically on whether electronic clinical quality measures (eCQMs) would benefit the program at some point in the future. We first raised the potential future consideration of electronically specified measures in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50104), and stated that we would continue to review the viability of including electronic measures. We are now specifically interested in stakeholder comments regarding the potential for the Program's future adoption of eCQMs. These measures use data from electronic health records (EHRs) and/or health information technology systems to measure health care quality. We believe eCQMs will allow for the improved measurement of processes, observations, treatments and outcomes. Measuring and reporting eCQMs provide information on the safety, effectiveness, and timeliness of care. We are also interested in adopting eCQMs because 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 attention to improving clinicians' and beneficiaries' experience when interacting with CMS programs. We believe eCQMs offer many benefits to clinicians and quality reporting and are an improvement over traditional quality measures because they leverage the EHR to generate chart-abstracted data, which is less resource intensive and likely to produce fewer human errors than traditional chart-abstraction.

We believe that our continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur.

We are inviting public comments and suggestions on future measures, including eCQMs, for the HAC Reduction Program.

K. Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272), establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days. The provisions of section 1886(h) of the Act are implemented in regulations at 42 CFR 413.75 through 413.83.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. Therefore, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit (that is, a cap) on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Proposed Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

Section 1886(h)(4)(H)(ii) of the Act authorizes the Secretary to prescribe rules that allow hospitals that form affiliated groups to elect to apply direct GME caps on an aggregate basis, and such authority applies for purposes of aggregating IME caps under section 1886(d)(5)(B)(viii) of the Act. Under such authority, the Secretary promulgated rules to allow hospitals that are members of the same Medicare GME affiliated group to elect to apply their direct GME and IME FTE caps on an aggregate basis. As specified in §§ 412.105(f)(1)(vi) and 413.79(f) of the regulations, hospitals that are part of the same Medicare GME affiliated group are permitted to apply their IME and direct GME FTE caps on an aggregate basis, and to temporarily adjust each hospital's caps to reflect the rotation of residents among affiliated hospitals during an academic year. Sections 413.75(b) and 413.79(f) specify the rules for Medicare GME affiliated groups. Generally, two or more hospitals may form a Medicare GME affiliated group if the hospitals are located in the same urban or rural area or in contiguous urban or rural areas, if they are under common ownership, or if they are jointly listed as program sponsors or major participating institutions in the same program. Sections 413.75(b) and 413.79(f) also address emergency Medicare GME affiliation agreements, which can apply in the event of a section 1135 waiver and if certain conditions are met.

For a new urban teaching hospital that qualifies for an adjustment to its FTE cap under § 412.105(f)(1)(vii) or § 413.79(e)(1), or both, § 413.79(e)(1)(iv) provides that the new urban hospital may enter into a Medicare GME affiliation agreement only if the resulting adjustment is an increase to its direct GME and IME FTE caps (for purposes of this discussion, the term ''urban'' is defined as that term is described at § 412.64(b) of the regulations). We adopted this policy in the FY 2006 IPPS final rule (70 FR 47452 through 47454). Prior to that final rule, new urban teaching hospitals were not permitted to participate in a Medicare GME affiliation agreement (63 FR 26333). In modifying our rules to allow new urban teaching hospitals to participate in Medicare GME affiliation agreements, we noted our concerns about such affiliation agreements (70 FR 47452). Specifically, we were concerned that hospitals with existing medical residency training programs could otherwise, with the cooperation of new teaching hospitals, circumvent the statutory FTE resident caps by establishing new medical residency programs in the new teaching hospitals solely for the purpose of affiliating with the new teaching hospitals to receive an upward adjustment to their FTE caps under an affiliation agreement. This would effectively allow existing teaching hospitals to achieve an increase in their FTE resident caps beyond the number allowed by their statutory caps (70 FR 47452). Accordingly, we adopted the restriction under § 413.79(e)(1)(iv). We refer readers to the FY 2006 IPPS final rule for a discussion of the regulatory history of this provision (70 FR 47452 through 47454).

We have received questions about whether two (or more) new urban teaching hospitals can form a Medicare GME affiliated group; that is, whether an affiliated group consisting solely of new urban teaching hospitals is permissible, considering that, under § 413.79(e)(1)(iv), a new urban teaching hospital may only enter into a Medicare GME affiliation agreement if the resulting adjustments to its direct GME and IME FTE caps are increases to those caps. The type of Medicare GME affiliated group contemplated under the regulation at § 413.79(e)(1)(iv) involves an existing teaching hospital(s) (a hospital with cap(s) based on training occurring in 1996) and a new teaching hospital(s), and therefore, we do not believe a Medicare GME affiliation agreement consisting solely of new urban teaching hospitals is permissible under § 413.79(e)(1)(iv). However, we believe it is important to provide flexibility with regard to Medicare GME affiliation agreements in light of the statutorily mandated caps on the number of FTE residents a hospital may

count for direct GME and IME payment purposes. As we noted in the FY 2006 IPPS final rule, while the rules we established in § 413.79(e)(1)(iv) were meant to prevent gaming on the part of existing teaching hospitals, we did not wish to preclude affiliations that clearly are designed to facilitate additional training at a new teaching hospital. We believe allowing two (or more) new urban teaching hospitals to form a Medicare GME affiliated group will enable these hospitals to provide residents training at their facilities with both the required and more varied training experiences necessary to complete their residency training programs. Furthermore, we believe the proposed change would facilitate increased training within local, smaller-sized communities because generally new urban teaching hospitals are smaller-sized, community-based hospitals compared with existing urban teaching hospitals, which are generally large academic medical centers. Accordingly, under our authority in section 1886(h)(4)(H)(ii) of the Act, we are proposing to revise the regulation to specify that new urban teaching hospitals (that is, hospitals that qualify for an adjustment under § 412.105(f)(1)(vii) or § 413.79(e)(1), or both) may form a Medicare GME affiliated group and therefore be eligible to receive both decreases and increases to their FTE caps.

We emphasize that the existing restriction under § 413.79(e)(1)(iv) would still apply to Medicare GME affiliated groups composed of existing and new urban teaching hospitals, given our concerns about gaming. We do not share the same level of concern in regards to Medicare GME affiliated groups consisting solely of new urban teaching hospitals because we believe these teaching hospitals are similarly situated in terms of size and scope of residency training programs and, therefore, less likely to participate in a Medicare GME affiliated group where the outcome of that agreement would only provide advantages to one of the participating hospitals. However, we still believe it is important to ensure that Medicare GME affiliation agreements entered into between new urban teaching hospitals are consistent with the intent of the Medicare GME affiliation agreement provision; that is, to promote the cross-training of residents at the participating hospitals and not to provide for an unfair advantage of one participating hospital at the expense of another hospital.

Therefore, we are proposing to revise § 413.79(e)(1)(iv) by designating the existing provision of paragraph (iv) as paragraph (A) and adding proposed paragraph (B) to specify that an urban hospital that qualifies for an adjustment to its FTE cap under this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap only if the decrease results from a Medicare GME affiliated group consisting solely of two or more urban hospitals that qualify to receive adjustments to their FTE caps under this paragraph (e)(1). Because Medicare GME affiliation agreements can only be entered into at the start of an academic year (that is, July 1), we are proposing that this proposed change would be effective beginning with affiliation agreements entered into for the July 1, 2019 through June 30, 2020 residency training year. We note that, if adopted, the proposed change discussed in this proposed rule would apply to both Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements.

3. Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule (75 FR 72212), we established regulations (42 CFR 413.79(o)) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010.

b. Notice of Closure of Affinity Medical Center, Located in Massillon, OH, and the Application Process—Round 11

CMS has learned of the closure of Affinity Medical Center, located in Massillon, OH (CCN 360151). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 11th round (''Round 11'') of the application and selection process. The table below contains the identifying information and IME and direct FTE GME resident caps for the closed teaching hospital, which is part of the Round 11 application process under section 5506 of the Affordable Care Act.

CCN	Provider name	City and state	CBSA code	Terminating date	IME FTE resident cap (including +/− MMA Sec. 422[1] and ACA Sec. 5503[2] adjustments)	Direct GME FTE resident cap (including +/− MMA Sec. 422[1] and ACA Sec. 5503[2] adjustments)
#151	Affinity Medical Center.	Massillon, OH	15940	February 11, 2018.	28.63 − 4.27 sec. 422 reduction − 2.00 sec. 5503 reduction = 22.36[3].	29.49 − 4.79 sec. 422 reduction − 2.22 sec. 5503 reduction = 22.48[4].

[1] Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

[2] Section 5503 of the Affordable Care Act of 2010, Public Law 111–148 and Public Law 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.

[3] Affinity Medical Center's 1996 IME FTE resident cap is 28.63. Under section 422 of the MMA, the hospital received a reduction of 4.27 to its IME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 2.00 to its IME FTE resident cap: 28.63 − 4.27 − 2.00 = 22.36.

[4] Affinity Medical Center's 1996 direct GME FTE resident cap is 29.49. Under section 422 of the MMA, the hospital received a reduction of 4.79 to its direct GME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 2.22 to its direct GME FTE resident cap: 29.49 − 4.79 − 2.22 = 22.48.

c. Notice of Closure of Baylor Scott & White Medical Center—Garland, Located in Garland, TX, and the Application Process—Round 12

CMS has learned of the closure of Baylor Scott & White Medical Center—Garland, located in Garland, TX (CCN 450280). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 12th round (''Round 12'') of the application and selection process. The table below contains the identifying information and the IME and direct GME FTE resident caps for the closed teaching hospital, which is part of the Round 12 application process under section 5506 of the Affordable Care Act:

CCN	Provider name	City and state	CBSA code	Terminating date	IME FTE resident cap (including +/− MMA Sec. 422 [1] and ACA Sec. 5503 [2] Adjustments)	Direct GME FTE resident cap (including +/− MMA Sec. 422 [1] and ACA Sec. 5503 [2] Adjustments)
450280	Baylor Scott & White Medical Center Garland.	Garland, TX	19124	February 28, 2018.	3.91 + 12.96 − 0.05 sec. 422 reduction − 4.30 sec. 5503 reduction = 12.52 [3].	3.91 + 14.09 − 1.88 sec. 422 reduction − 2.59 sec. 5503 reduction = 13.53 [4].

[1] Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
[2] Section 5503 of the Affordable Care Act, Public Law 111–148 and Public Law 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.
[3] Baylor Scott & White Medical Center Garland's 1996 IME FTE resident cap is 3.91. The hospital received a new program IME FTE resident cap add-on of 12.96. Under section 422 of the MMA, the hospital received a reduction of 0.05 to its IME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 4.30 to its IME FTE resident cap: 3.91 + 12.96 − 0.05 − 4.30 = 12.52.
[4] Baylor Scott & White Medical Center Garland's 1996 direct GME FTE resident cap is 3.91. The hospital received a new program direct GME FTE resident cap add-on of 14.09. Under section 422 of the MMA, the hospital received a reduction of 1.88 to its direct GME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 2.59 to its direct GME FTE resident cap: 3.91 + 14.09 − 1.88 − 2.59 = 13.53.

d. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notification to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the above hospitals' FTE resident caps must submit applications (Section 5506 Application Form posted on Direct Graduate Medical Education (DGME) website as noted at the end of this section) directly to the CMS Central Office no later than July 23, 2018. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the July 23, 2018 deadline date. It is *not* sufficient for applications to be postmarked by this date.

We note that an applying hospital may apply for either or both of the two rounds of section 5506 slot applications that are being announced in this proposed rule. However, a separate application must be submitted for each round for which a hospital wishes to apply.

After an applying hospital sends a hard copy of a section 5506 slot application to the CMS Central Office mailing address, the hospital is strongly encouraged to notify the CMS Central Office of the mailed application by sending an email to: *ACA5506application@cms.hhs.gov*. In the email, the hospital should state: ''On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round [11 or 12] due to the closure of [Affinity Medical Center or Baylor Scott & White Medical Center Garland]. If you have any questions, please contact me at [insert phone number] or [insert your email address].'' An applying hospital should *not* attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy application that is being mailed to the CMS Central Office.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html* to download a copy of the section 5506 application form (Section 5506 CMS Application Form) that hospitals must use to apply for slots under section 5506 of the Affordable Care Act. Hospitals should also access this same website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

L. 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 below). Section 15003 also requires that, no later than 120 days after enactment of Public Law 114–255, the Secretary must 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 the Affordable Care Act is not exceeded. In this

proposed rule, we are providing a summary of the previous legislative provisions and their implementation; a description of the provisions of section 15003 of Public Law 114–255; our final policies for implementation; the finalized budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255, including a discussion of the budget neutrality methodology used in previous final rules for periods prior to the extension period; and an update on the reconciliation of actual and estimated costs of the demonstration for previous years (2011, 2012, and 2013).

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), 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(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost reporting periods beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the demonstration program and converted to CAH status. This left 9 hospitals participating at that time. In 2008, we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These 4 additional hospitals began under the demonstration payment methodology with the hospitals' first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals withdrew from the demonstration program during CYs 2009 and 2010. In CY 2011, one hospital among this original set of participating hospitals withdrew. These actions left 7 of the hospitals that were selected to participate in either 2004 or 2008 participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, changing the Rural Community Hospital Demonstration program in several ways. First, the Secretary was required 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. Further, the Affordable Care Act required the Secretary to provide for the continued participation of such rural community hospital 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, the Affordable Care Act required, during the 5-year extension period, that the Secretary expand the number of States with low population densities determined by the Secretary to 20. Further, the Secretary was required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period. The Affordable Care Act also allowed not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period.

We published a solicitation for applications for additional participants in the Rural Community Hospital Demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). The 20 States with the lowest population density that were eligible for the demonstration program were: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). Sixteen new hospitals began participation in the demonstration with the first cost reporting period beginning on or after April 1, 2011.

In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital of the set selected in 2011 withdrew from the demonstration, which left 22 hospitals participating in the demonstration, effective July 1, 2013, all of which continued their participation through December 2014. Starting from that date and extending through the end of FY 2015, the 7 hospitals that were selected in either 2004 or 2008 ended their scheduled 5-year periods of performance authorized by the Affordable Care Act on a rolling basis. Likewise, the participation period for the 14 hospitals that entered the demonstration following the mandate of the Affordable Care Act and that were still participating ended their scheduled periods of performance on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. (One hospital among this group closed in October 2015.)

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 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. 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) which requires 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 the Affordable Care Act). Paragraph 410A(g)(6)(B) provides that, in determining which hospitals submitting an application pursuant to this solicitation are 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 may also 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 the 21st Century Cures Act (December 13, 2016), as well as the population density of the State in which the rural community hospital is located.

b. Solicitation for Additional Participants

As required under section 15003 of Public Law 114–255, we issued a solicitation for additional hospitals to participate in the demonstration. We released this solicitation on April 17, 2017. As described in the FY 2018 IPPS/LTCH PPS proposed rule, the solicitation identified the 20 States with the lowest population density according to the population estimates from the Census Bureau for 2013, from the *ProQuest Statistical Abstract of the United States, 2015.* These 20 States are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Vermont, and Wyoming. Applications were due May 17, 2017. Applications were assessed in accordance with the information requested in the solicitation; that is, the problem description, plan for financial viability, goals for the demonstration, contributions to quality of care, and collaboration with other providers and organizations. In accordance with the authorizing statute, closure of hospitals within the State of the applicant hospital and population density were considered in assessing applications.

c. Terms of Participation for the Extension Period Authorized by Public Law 114–255

In the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19994), we stated that our goal was to finalize the selection of participants for the extension period authorized by Public Law 114–255 by June 2017, in time to include in the FY 2018 IPPS/LTCH PPS final rule an estimate of the costs of the demonstration during FY 2018 and the resulting budget neutrality offset amount, for these newly participating hospitals, as well as for those hospitals among the previously participating hospitals that decided to participate in the extension period. (The specific method for ensuring budget neutrality under section 410A of Public Law 108–173 was described in the FY 2018 IPPS proposed rule, consistent with general policies adopted in previous years). We indicated that upon announcing the selection of new participants, we would confirm the start dates for the periods of performance for these newly selected hospitals and for previously participating hospitals. We stated, on the other hand, that if final selection were not to occur by June 2017, we would not be able to include an estimate of the costs of the demonstration or an estimate of the budget neutrality offset amount for FY 2018 for these additional hospitals in the FY 2018 IPPS/LTCH PPS final rule.

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 the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the date the period of performance under the first 5-year extension period ended. However, by the time of the FY 2018 IPPS/LTCH PPS final rule, we had not been able to verify which among the previously participating hospitals would be continuing participation, and thus were not able to estimate the costs of the demonstration for that year's final rule. We stated in the final rule that we would instead include the estimated costs of the demonstration for all participating hospitals for FY 2018, along with those for FY 2019, in the budget neutrality offset amount for the FY 2019 proposed and final rules.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act have 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. Thus, 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, 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, as well, that each of these newly participating hospitals would begin its 5-year period of participation effective the start of the first cost reporting period on or after October 1, 2017. Thus, 30 hospitals are participating in the demonstration during FY 2018.

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 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, 77 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 have 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 have 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 2010 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 will 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 will 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. As we described in the FY 2018 final rule, we will be incorporating several distinct components into the budget neutrality offset amount for FY 2019:

- 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 has been applied to the date following the end date of its period of performance for the first extension period to the date of conversion. As we finalized in the FY 2018 IPPS/LTCH PPS final rule, we are applying a specific methodology for ensuring that the budget neutrality requirement under section 410A of Public Law 108–173 is met. To reflect the costs of the demonstration for the previously participating hospitals, for their cost reporting periods starting in FYs 2015, 2016, and 2017, we will use available finalized cost reports that detail the actual costs of the demonstration for each of these fiscal years. We will then incorporate these amounts in the budget neutrality offset amount to be included in a future IPPS final rule. We expect to do this in either FY 2020 or FY 2021, based on the availability of finalized reports.
- In addition, we will include 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. For FY 2019,

we will include the estimated costs of the demonstration for FYs 2018 and 2019 in accordance with the methodology finalized in the FY 2018 IPPS/LTCH PPS final rule.

• Similar to previous years, in order to meet the budget neutrality requirement in section 410A(c)(2) of Public Law 108–173 with respect to the second 5-year extension period, we will continue to implement the policy according to when finalized cost reports become available for each of the second 5 years of the 10-year extension period for the newly participating hospitals and for cost reporting periods starting in or after FY 2018 that occur during the second 5-year extension period for the previously participating hospitals. We will determine the difference between the actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the corresponding fiscal year IPPS final rule, and include that difference either as a positive or negative adjustment in the upcoming year's final rule.

As described earlier, we have calculated this difference for FYs 2005 through 2010 between the actual costs of the demonstration, as determined from finalized cost reports and estimated costs of the demonstration set forth in the applicable IPPS final rules for these years, and then incorporated that amount into the budget neutrality offset amount for an upcoming fiscal year. In this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to include this difference based on finalized cost reports for FYs 2011, 2012, and 2013 in the budget neutrality offset adjustment to be applied to the national IPPS rates for FY 2019. In future IPPS rules, we will continue this reconciliation, calculating the difference between actual and estimated costs for the remaining years of the first extension period (that is, FYs 2014 through 2016), and, as described above, the further years of the demonstration under the second extension period, applying this difference to the budget neutrality offset adjustments identified in future years' final rules.

(2) Methodology for the Budget Neutrality Adjustment for the Previously Participating Hospitals for FYs 2015 Through 2017

As we finalized in the FY 2018 IPPS/LTCH PPS final rule, for each previously participating hospital, the cost-based payment methodology under the demonstration will be applied to the date immediately following the end date of its period of performance for the first 5-year extension period. We are applying the same methodology as previously finalized to account for the costs of the demonstration and ensure that the budget neutrality requirement under section 410A of Public Law 108–173 is met for the previously participating hospitals for cost reporting periods starting in FYs 2015, 2016, and 2017. We believe it is appropriate to determine such a specific methodology applicable to these cost reporting periods because they are a component of the payment methodology for the demonstration under the second extension period, authorized by section 15003 of Public Law 114–255, yet encompass the provision of services and incurred costs occurring prior to the start of FY 2018, when the terms of continuation for these hospitals under this second extension period were finalized.

To reflect the costs of the demonstration for the previously participating hospitals for their cost reporting periods under the second extension period starting before FY 2018 (that is, cost reporting periods starting in FYs 2015, 2016, and 2017), we will determine the actual costs of the demonstration for each of these fiscal years when finalized cost reports become available. Thus, for a hospital with an end date of June 30, 2015 for the first participation period, we will determine from finalized cost reports the specific amount contributing to the total costs of the demonstration for the 3 cost reporting years from July 1, 2015 through June 30, 2018; for a hospital with an end date of June 30, 2016, we will determine from finalized cost reports the amount contributing to costs of the demonstration for the 2 cost reporting periods from July 1, 2016 through June 30, 2018.

We note that, for these hospitals, this last cost report period may include services occurring since the enactment of Public Law 114–255 and also during FY 2018. However, we believe that applying a uniform method for determining costs across a cost report year would be more reasonable from the standpoint of operational feasibility and consistent application of cost determination principles. Under this approach, we will incorporate these amounts for the previously participating hospitals for cost reporting periods starting in FYs 2015, 2016, and 2017 into a single amount to be included in the calculation of the budget neutrality offset amount to the national IPPS rates in a future final rule after such finalized cost reports become available. As noted above, we expect to do this in FY 2020 or FY 2021.

(3) Methodology for Estimating Demonstration Costs for FY 2018

As discussed earlier, in this FY 2019 IPPS/LTCH PPS proposed rule, as a component of the overall budget neutrality methodology, 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. As explained above, for FY 2019, we will be including the estimated costs of the demonstration for FYs 2018 and 2019.

As described in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38286), we will incorporate a specific calculation to account for the fact that the cost reporting periods for the participating hospitals applicable to the estimate of the costs of the demonstration for FY 2018 would start at different points of time during FY 2018. That is, we will be prorating estimated reasonable cost amounts and amounts that would be paid without the demonstration for FY 2018 according to the fraction of the number of months within the hospital's cost reporting period starting in FY 2018 that fall within the total number of months in the fiscal year. For example, if a hospital started its cost reporting period on January 1, 2018, we will multiply the estimated cost and payment amounts, derived as described below, by a factor of 0.75. (In this discussion of how the overall calculations are conducted, this factor is referred to as ''the hospital-specific prorating factor.'') The methodology for calculating the amount applicable to FY 2018 to be incorporated into the budget neutrality offset amount for FY 2019 was described in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38286) and proceeds according to the following steps:

Step 1: For each of the 30 participating hospitals, we will identify the reasonable cost amount calculated under the reasonable cost 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 2016.) We believe these most recent available cost reports to be an accurate predictor of the costs of the demonstration in FY 2018 because they give us a recent picture of the participating hospitals' costs.

For each hospital, we will multiply each of these amounts by the FY 2017

and 2018 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. For each of FYs 2017 and 2018, we would then multiply these products (for covered inpatient hospital services, including swing beds), of the estimated reasonable cost amounts for each participating hospital and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment. The result for each participating hospital would be the general estimated reasonable cost amount for covered inpatient hospital services for FY 2018.

Consistent with our methods in previous years for formulating this estimate, we will apply the IPPS market basket percentage increases for FYs 2017 through 2018 to the applicable estimated reasonable cost amounts (described above) in order to model the estimated FY 2018 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. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and is intended to reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledge the possibility that inpatient caseloads for small hospitals may fluctuate, and therefore we are incorporating into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the participating hospitals, we will identify the estimated amount that would otherwise be paid in FY 2018 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. We then will multiply each of these hospital-specific amounts (for covered inpatient hospital services including swing-bed services), by the FYs 2017 and 2018 (in accordance with the discussion above) IPPS applicable percentage increases. This methodology differs from Step 1, in which we will be applying 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 would 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. Then, for the same reasons discussed in Step 1, we would multiply these hospital-specific products of the applicable estimated payments that generally would otherwise be made without the demonstration and the IPPS applicable percentage increases applicable to the years involved by the 3-percent annual volume adjustment for each of FYs 2017 through 2018.

Step 3: We will subtract the amounts derived in Step 2 from the amount derived in Step 1. According to our methodology, each of these resulting amounts indicates the difference for the hospital (for covered inpatient hospital services, including swing beds), which would be the general estimated amount of the costs of the demonstration for FY 2018.

Step 4: For each hospital, we will multiply the amount derived in Step 3 by the hospital-specific prorating factor. The resulting amount represents for each hospital the cost of the demonstration applicable to the cost reporting period beginning in FY 2018, on the basis of which the specific component of the budget neutrality offset amount applicable to FY 2018 will be derived.

Step 5: We will then sum the hospital-specific amounts derived in Step 4 across all 30 hospitals participating in the demonstration in FY 2018. This resulting sum will be the proposed estimated costs of the demonstration applicable to FY 2018 to be incorporated in the budget neutrality offset amount for rulemaking in FY 2019.

For this proposed rule, the resulting amount applicable to FY 2018 is $33,254,247, which we are proposing to include in the budget neutrality offset adjustment for FY 2019. This estimated amount is based on the specific assumptions regarding the data sources used, that is, ''as submitted'' recently available cost reports and historical and specific update factors described for cost, payment, and volume. If updated data become available prior to the FY 2019 IPPS/LTCH PPS final rule, we will use them to the extent appropriate to estimate the costs for the demonstration program applicable to FY 2018 in accordance with our methodology for determining the budget neutrality estimate. In particular, we are evaluating the appropriateness of the 3-percent annual volume adjustment in light of empirical trends specific to the participating hospitals. Therefore, the estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

(4) Methodology for Estimating Demonstration Costs for FY 2019

To estimate the costs of the demonstration for FY 2019, we will apply two differences specific to the application of adjustment factors to the methodology described for FY 2018. We will use the same set of ''as submitted'' cost reports in determining preliminary cost and payment amounts for covered inpatient hospital services. However, in updating these amounts to reflect increases in cost, payment, and volume, our methodology for determining the component of the budget neutrality offset amount applicable to FY 2019 entails applying the market basket percentage increase and applicable percentage increase for FY 2019, in addition to these update factors for FYs 2017 and 2018. The proposed amounts for FY 2019 for these respective update factors are found in sections IV.L.4.c.(2) and (3) of the preamble to this proposed rule. In addition, consistent with the methodology for FY 2018, we would again apply the 3-percent volume adjustment to reflect possible increases for FY 2019, in addition to applying this factor for each of FYs 2017 and 2018. In addition, because we are expecting all of the participating hospitals to participate for the entire 12-month period encompassing FY 2019, there will be no application of any prorating factor in determining the estimated costs of the demonstration for FY 2019.

For this proposed rule, the resulting amount for FY 2019 is $78,409,842, which we are likewise proposing to include in the budget neutrality offset adjustment for FY 2019. This estimated amount is based on the specific assumptions regarding the data sources used, that is, ''as submitted'' recently available cost reports and historical and proposed update factors for cost, payment, and volume. If updated data become available prior to the FY 2019 IPPS/LTCH PPS final rule, we will use them to the extent appropriate to estimate the costs for the demonstration program in FY 2019 in accordance with our finalized methodology. Again, we are considering the appropriateness of applying the 3-percent annual volume adjustment. Therefore, the estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

(5) Reconciling Actual and Estimated Costs for the Years of the Extension Period

Similar to previous years, as finalized in the FY 2018 IPPS/LTCH PPS final rule, we plan to operationalize the second specific component to the budget neutrality requirement. That is, when finalized cost reports become available for each of the second 5 years of the 10-year extension period for the newly participating hospitals and for cost reporting periods starting in or after FY 2018 that occur during the second 5-year extension period for the previously participating hospitals, we will calculate the difference between the actual costs of the demonstration as determined from these finalized cost reports and the estimated cost indicated in the corresponding fiscal year IPPS final rule, and include that difference either as a positive or negative adjustment in the upcoming year's final rule.

Therefore, in keeping with the methodologies used in previous final rules, we will continue to use a methodology for calculating the budget neutrality offset amount for the second 5 years of the 10-year extension period consisting of two components: (1) The estimated demonstration costs in the upcoming fiscal year (as described above); and (2) the amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports became available for that year) differed from the budget neutrality offset amount finalized in the corresponding year's IPPS final rule.

d. Reconciling Actual and Estimated Costs of the Demonstration for Previous Years (2011, 2012, and 2013)

As described earlier, we have calculated the difference for FYs 2005 through 2010 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. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57037), we finalized a proposal to reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration was scheduled to end December 31, 2016. In that final rule, we stated that we believed it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. We stated that such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration would represent an administratively streamlined method, allowing for the determination of any appropriate adjustment to the IPPS rates and obviating the need for multiple, fiscal year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we stated that we expected any such analysis would be conducted in FY 2020.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38287), with the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we modified the plan outlined in the FY 2017 IPPS/LTCH PPS final rule, and instead returned to the general procedure in previous final rules; that is, as finalized cost reports become available, we would determine the amount by which the actual costs of the demonstration for an earlier, given year differ from the estimated costs for the demonstration set forth in the IPPS final rule for the corresponding fiscal year, and then incorporate that amount into the budget neutrality offset amount for an upcoming fiscal year. We finalized a policy that if the actual costs of the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference would be added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the final rule. Likewise, we finalized a policy that 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 would be subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for an upcoming fiscal year. However, given that this adjustment for specific years could be positive or negative, we would combine this reconciliation for multiple prior years into one adjustment to be applied to the budget neutrality offset amount for a single fiscal year, thus reducing the possibility of both positive and negative adjustments to be applied in consecutive years, and enhancing administrative feasibility. Specifically, when finalized cost reports for FYs 2011, 2012, and 2013 are available, we stated that we would include this difference for these years in the budget neutrality offset adjustment to be applied to the national IPPS rates in a future final rule. We stated that we expected that this would occur in FY 2019. We also stated that when finalized cost reports for FYs 2014 through 2016 are available, we would include the difference between the actual costs as reflected on these cost reports and the amounts included in the budget neutrality offset amounts for these fiscal years in a future final rule. We stated that we plan to provide an update in a future final rule regarding the year that we would expect that this analysis would occur.

Therefore, in this proposed rule, we are identifying the differences between the total cost of the demonstration as indicated on finalized FY 2011 and 2012 cost reports and the estimates for the costs of the demonstration for the corresponding year in each of these years' final rules, and we are proposing to adjust the current year's budget neutrality offset amount by the combined difference. If any information relevant to the determination of these amounts (for example, a cost report reopening) would necessitate a revision of these amounts, we will make the appropriate change and include the determination in the FY 2019 IPPS/LTCH PPS final rule. Furthermore, if the needed costs reports are available in time for the FY 2019 IPPS/LTCH PPS final rule, we will also identify the difference between the total cost of the demonstration based on finalized FY 2013 cost reports and the estimates for the costs of the demonstration for that year, and incorporate that amount into the budget neutrality offset amount for FY 2019.

Currently, finalized cost reports are now available for the 16 hospitals that completed a cost reporting period beginning in FY 2011 according to the demonstration cost-based payment methodology. We note that the estimate of the costs of the demonstration for FY 2011 that was incorporated into the budget neutrality offset amount was formulated prior to the selection of hospitals under the expansion of the demonstration authorized by the Affordable Care Act. Accordingly, we based the estimate of the costs of the demonstration for FY 2011 on projected costs for 30 hospitals, the maximum number allowed by the authorizing statute in the Affordable Care Act. The actual costs of the demonstration for FY 2011 (that is, the amount from finalized cost reports for the 16 hospitals that were paid under the demonstration payment methodology for cost reporting periods with start dates during FY

2011), fell short of the estimated amount that was finalized in the FY 2011 IPPS/LTCH PPS final rule for FY 2011 by $29,971,829.

In addition, finalized cost reports for the 23 hospitals that completed a cost reporting period under the demonstration payment methodology beginning in FY 2012 are also now available. The actual costs of the demonstration as determined from these finalized cost reports fell short of the estimated amount that was finalized in the FY 2012 final rule by $8,500,373.

We note that, for this proposed rule, the amounts identified for the actual cost of the demonstration for each of FYs 2011 and 2012 (determined from current finalized cost reports) is less than the amounts that were identified in the final rule for these fiscal years. Therefore, in keeping with previous policy finalized in similar situations when the costs of the demonstration fell short of the amount estimated in the corresponding year's final rule, we will be including this component as a negative adjustment to the budget neutrality offset amount for the current fiscal year.

e. Total Proposed Budget Neutrality Offset Amount for FY 2019

Therefore, for this FY 2019 IPPS/LTCH PPS proposed rule, we are incorporating the following components into the calculation of the total budget neutrality offset for FY 2019:

Step 1: The amount determined under subsection IV.4.c.(3) of the preamble of this proposed rule, representing the difference applicable to FY 2018 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to participating hospitals for covered inpatient hospital services and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. The determination of this amount includes prorating to reflect for each participating hospital the fraction of the number of months for the cost report year starting in FY 2018 falling into the overall 12 months of the fiscal year. This estimated amount is $33,254,247.

Step 2: The amount, determined under section IV.4.c.(4) of the preamble of this proposed rule representing the corresponding difference of these estimated amounts for FY 2019. No prorating is applied in the determination of this amount. This estimated amount is $78,409,842.

Step 3: The amount determined under section IV.4.d. of the preamble of this proposed rule according to which the actual costs of the demonstration for FY 2011 for the 16 hospitals that completed a cost reporting period beginning in FY 2011 differ from the estimated amount that was incorporated into the budget neutrality offset amount for FY 2011 in the FY 2011 IPPS/LTCH PPS final rule. Analysis of this set of cost reports shows that the actual costs of the demonstration fell short of the estimated amount finalized in the FY 2011 IPPS/LTCH PPS final rule by $29,971,829.

Step 4: The amount, also determined under subsection IV.4.d. of the preamble of this proposed rule according to which the actual costs for the demonstration for FY 2012 for the 23 hospitals that completed a cost reporting period beginning in FY 2012 differ from the estimated amount in the FY 2012 final rule. Analysis of this set of cost reports shows that the actual costs of the demonstration for FY 2012 fell short of the estimated amount finalized in the FY 2012 IPPS/LTCH PPS final rule by $8,500,373.

In keeping with previously finalized policy, we will be applying these differences, according to which the actual costs of the demonstration for each of FYs 2011 and 2012 fell short of the estimated amount determined in the final rule for each of these fiscal years, by reducing the budget neutrality offset amount to the national IPPS rates for FY 2019 by these amounts.

Thus, for FY 2019, the total budget neutrality offset amount that we are proposing to apply is: The amount determined under Step 1 ($33,254,247) plus the amount determined under Step 2 ($78,409,842) minus the amount determined under Step 3 ($29,971,829) minus the amount determined under Step 4 ($8,500,373). This total is $73,191,887. If updated data become available prior to the FY 2019 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2019. Therefore, the amount of the budget neutrality offset amount may change in the FY 2019 IPPS/LTCH PPS final rule. Furthermore, if the needed costs reports are available in time for the FY 2019 IPPS/LTCH PPS final rule, we will also identify the difference between the total cost of the demonstration based on finalized FY 2013 cost reports and the estimates for the costs of the demonstration for that year, and incorporate that amount into the budget neutrality offset amount for FY 2019.

In addition, in accordance with the policy finalized in the FY 2018 final IPPS/LTCH PPS final rule, we will incorporate the actual costs of the demonstration for the previously participating hospitals for cost reporting periods starting in FYs 2015, 2016, and 2017 into a single amount to be included in the calculation of the budget neutrality offset amount to the national IPPS rates in a future final rule after such finalized cost reports become available. We expect to do this in FY 2020 or FY 2021.

M. Proposed Revision of Hospital Inpatient Admission Orders Documentation Requirements Under Medicare Part A

1. Background

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68426 through 68433), we solicited public comments for potential policy changes to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between hospital admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50942), we adopted a set of policies widely referred to as the ''2 midnight'' payment policy. Among the finalized changes, we codified through regulations at 42 CFR 412.3 the longstanding policy that a beneficiary becomes a hospital inpatient if formally admitted pursuant to the order of a physician (or other qualified practitioner as provided in the regulations) in accordance with the hospital conditions of participation (CoPs). In addition, we required that a written inpatient admission order be present in the medical record as a specific condition of Medicare Part A payment. In response to public comments that the requirement of a written admission order as a condition of payment is duplicative and burdensome on hospitals, we responded that the physician order reflects affirmation by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary, and the ''order serves the unique purpose of initiating the inpatient admission and documenting the physician's (or other qualified practitioner as provided in the regulations) intent to admit the patient, which impacts its required timing.'' Therefore, we finalized the policy requiring a written inpatient order for all hospital admissions as a specific condition of payment. We acknowledged that in the extremely rare circumstance the order to admit is missing or defective, yet the intent, decision, and recommendation of the

ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record, medical review contractors are provided with discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record.

2. Proposed Revisions Regarding Admission Order Documentation Requirements

Despite the discretion granted to medical reviewers to determine that admission order information derived from the medical record constructively satisfies the requirement that a written hospital inpatient admission order is present in the medical record, as we have gained experience with the policy, it has come to our attention that some otherwise medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders. Common technical discrepancies consist of missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge. We have become aware that, particularly during the case review process, these discrepancies have occasionally been the primary reason for denying Medicare payment of an individual claim. In looking to reduce unnecessary administrative burden on physicians and providers and having gained experience with the policy since it was implemented, we have concluded that if the hospital is operating in accordance with the hospital CoPs, medical reviews should primarily focus on whether the inpatient admission was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay. It was not our intent when we finalized the admission order documentation requirements that they should by themselves lead to the denial of payment for otherwise medically reasonable necessary inpatient stay, even if such denials occur infrequently.

Therefore, we are proposing to revise the admission order documentation requirements by removing the requirement that written inpatient admission orders are a specific requirement for Medicare Part A payment. Specifically, we are proposing to revise the inpatient admission order policy to no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare Part A payment. Hospitals and physicians are already required to document relevant orders in the medical record to substantiate medical necessity requirements. If other available documentation, such as the physician certification statement when required, progress notes, or the medical record as a whole, supports that all the coverage criteria (including medical necessity) are met, and the hospital is operating in accordance with the hospital conditions of participation (CoPs), we believe it is no longer necessary to also require specific documentation requirements of inpatient admission orders as a condition of Medicare Part A payment. This proposal does not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for inpatient admission. While this continues to be a requirement, as indicated earlier, technical discrepancies with the documentation of inpatient admission orders have led to the denial of otherwise medically necessary inpatient admission. To reduce this unnecessary administrative burden on physicians and providers, we are no longer requiring that the specific documentation requirements of inpatient admission orders be present in the medical record as a condition of Medicare Part A payment.

Therefore, we are proposing to revise the regulations at 42 CFR 412.3(a) to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A. We note that we are not proposing any changes with respect to the ''2 midnight'' payment policy.

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)) x (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 2019

The proposed annual update to the national capital Federal rate, as provided for in § 412.308(c), for FY 2019 is discussed in section III. of the Addendum to this proposed rule.

In section II.D. of the preamble of this 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 2019, 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).

VI. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2019

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 use 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), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also use 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 2019, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2019 percentage increase in the 2014-based IPPS operating market basket. Based on IGI's 2017 fourth quarter forecast, for this proposed rule, we estimate that the 2014-based IPPS operating market basket update for FY 2019 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the FY 2019 rate-of-increase percentage that would be applied to the FY 2018 target amounts in order to calculate the FY 2019 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 2.8 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are proposing that if more recent data become available for the final rule, we would use them to calculate the final IPPS operating market basket update for FY 2019.

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 section 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 2019, in accordance with § 412.22(i) and § 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2019, the update to the target amount for long-term care neoplastic disease 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 2019, which would be equal to the percentage increase in the hospital market basket index. As described earlier, for this proposed rule, the percentage increase in the hospital market basket index 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, for this proposed rule, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2019 is 2.8 percent, which is based on IGI's 2017 fourth quarter forecast. Furthermore, we are proposing that if more recent data become available for the final rule, we would use that updated data to calculate the IPPS operating market basket update for FY 2019.

B. Proposed Changes to Regulations Governing Satellite Facilities

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294), we finalized a change to our hospital-within-hospital (HwH) regulations at 42 CFR 412.22(e) to only require, as of October 1, 2017, that IPPS-excluded HwHs that are co-located with IPPS hospitals comply with the separateness and control requirements in those regulations. We adopted this change because we believe that the policy concerns that underlay the previous HwH regulations (that is, inappropriate patient shifting and hospitals acting as illegal de facto units) are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other, in large part due to changes that have been made to the way most types of IPPS-excluded hospitals are paid under Medicare. In response to our proposal on this issue, we received some public comments requesting that CMS make analogous changes to the rules governing satellite facilities, and we responded in the FY 2018 IPPS/LTCH PPS final rule that we would take that request under consideration for future rulemaking.

Under 42 CFR 412.22(h), a satellite facility is defined as part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

There are significant similarities between the definition of a satellite facility and the definition of an HwH as those definitions relate to their co-location with host hospitals. Our policies on satellite facilities have also been premised on many of the same concerns that formed the basis for our HwH policies. That is, the separateness and control policies for satellite facilities at 42 CFR 412.22(h) were aimed at mitigating our concern that the co-location of a satellite facility and a host hospital raised a potential for inappropriate patient shifting that we believed could be guided more by attempts to maximize Medicare reimbursements than by patient welfare (71 FR 48107). However, just as changes to the way most types of IPPS-excluded hospitals are paid under Medicare have sufficiently moderated this concern in situations where IPPS-excluded hospitals are co-located with each other, we believe that these payment changes also sufficiently moderate these concerns in situations where IPPS-excluded satellite facilities are co-located with IPPS-excluded host hospitals. Furthermore, we believe that there is no compelling policy rational for treating satellite facilities and HwHs differently on the issue of separateness and control because there is no meaningful distinction between these types of facilities that would justify a satellite facility having to comply with separateness and control requirements in a situation in which an HwH would not be required to comply (we note that the separateness and control requirements for satellite facilities are not the same as those for HwHs; however, they are similar). Therefore, we are proposing to revise our regulations at § 412.22(h)(2)(iii)(A) to only require IPPS-excluded satellite facilities that are co-located with IPPS hospitals to comply with the separateness and control requirements. Specifically, we are proposing to add a new paragraph (*4*) to § 412.22(h)(2)(iii)(A) to specify that, effective on or after October 1, 2018, a satellite facility that is part of an IPPS-excluded hospital that provides inpatient services in a building also used by an IPPS-excluded hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS-excluded hospital, is not required to meet the criteria in § 412.22(h)(2)(iii)(A)(*1*) through (*3*) in order to be excluded from the IPPS. Proposed new § 412.22(h)(2)(iii)(A)(*4*) would also specify that a satellite facility that is part of an IPPS-excluded hospital which is located in a building also used by an IPPS hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS hospital, is still required to meet the criteria in § 412.22 (h)(2)(iii)(A)(*1*) through (*3*) in order to be excluded from the IPPS.

As described in further detail in section VI.C. of the preamble of this proposed rule, we are proposing that, for cost reporting periods beginning on or after October 1, 2019, an IPPS excluded hospital would no longer be precluded from having an excluded psychiatric and/or rehabilitation unit. Consistent with our proposed changes to the regulations governing satellite facilities discussed earlier, we also are proposing to add new paragraph (iv) to § 412.25(e)(2) to specify that an IPPS-excluded satellite facility of an IPPS-excluded unit of an IPPS-excluded hospital would not have to comply with the separateness and control requirements so long as the satellite of the excluded unit is not co-located with an IPPS hospital, and to make conforming revisions to § 412.25(e)(2)(iii)(A) to subject that provision to paragraph (iv).

It is important to point out that payment rules, such as the HwH or satellite facility rules, never waive or supersede the requirement that all hospitals must comply with the hospital conditions of participation (CoPs). All hospitals, regardless of payment status, must always demonstrate separate and independent compliance with the

hospital CoPs, even when an entire hospital or a part of a hospital is located in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. We further note that this proposal would not affect IPPS-excluded satellite facilities that are co-located with IPPS hospitals that are currently grandfathered under § 412.22 (h)(2)(iii)(A)(2). Those satellite facilities would continue to maintain their IPPS-excluded status without complying with the separateness and control requirements so long as all applicable requirements at § 412.22(h) are met.

C. Proposed Changes to Regulations Governing Excluded Units of Hospitals

Under existing regulations at 42 CFR 412.25, an excluded psychiatric or rehabilitation unit cannot be part of an institution that is excluded in its entirety from the IPPS. These regulations were codified in the FY 1994 IPPS final rule (58 FR 46318). However, as we explained in that rule, while this prohibition was not explicitly stated in the regulations until that time, the prohibition had been our longstanding policy. This policy was adopted at that time because it would have been redundant to allow an IPPS-excluded hospital to have an IPPS-excluded unit because both the hospital and the unit would have been paid under the same Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) payment system methodology, described in section VI.A. of this proposed rule. In addition, we were concerned about the possibility of IPPS-excluded hospitals artificially inflating their target amounts by operating IPPS-excluded units (58 FR 46318).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294), we finalized a change to the HwH regulations to only require, as of October 1, 2017, that IPPS-excluded HwHs that are co-located with IPPS hospitals comply with the separateness and control requirements in those regulations. In this proposed rule, we are proposing to make similar changes to the regulations governing satellite facilities, which would allow these facilities, including satellite facilities of hospital units, to maintain their IPPS-excluded status without complying with the separateness and control requirements so long as they are not co-located with an IPPS hospital. In conjunction with the HwH regulation changes and the proposed satellite facilities regulation changes, and as part of our continued efforts to reduce regulatory burden and achieve program simplification, we believe it is appropriate to propose changes to our regulations for the establishment of IPPS-excluded units in IPPS-excluded hospitals. Given the introduction of prospective payment systems for both inpatient rehabilitation facilities and units (collectively IRFs) and psychiatric hospitals and units (collectively IPFs), we no longer believe it is redundant for an IPPS-excluded hospital to have an IPPS-excluded unit, nor is it possible for IPPS-excluded hospitals to use units to artificially inflate their target amounts, because Medicare payment for discharges from the units would not be based on reasonable cost. For example, under our proposal, an LTCH operating a psychiatric unit would receive payment under the IPF PPS for discharges from the psychiatric unit and payment under the LTCH PPS for discharges not from the psychiatric unit. Payment for discharges from the psychiatric unit would be made under the IPF PPS rather than the LTCH PPS because Medicare pays for services provided by an excluded hospital unit under a separate payment system from the hospital in which the unit is a part. For the purposes of payment, services furnished by a unit are considered to be inpatient hospital services provided by the unit and not inpatient hospital services provided by the hospital operating the unit.

In this proposed rule, we are proposing to revise § 412.25(a)(1)(ii) to specify that the requirement that an excluded psychiatric or rehabilitation unit cannot be part of an IPPS-excluded hospital is only effective through cost reporting periods beginning on or before September 30, 2019. Under this proposal, effective with cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital would be permitted to have an excluded psychiatric and/or rehabilitation unit. In addition, we are proposing to revise § 412.25(d) to specify that an IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an IRF may not have an IRF unit). We believe that this proposed change would be consistent with the current preclusion in § 412.25(d) that prevents one hospital from having more than one of the same type of IPPS-excluded unit. However, we note that if these proposed changes to the payment rules are finalized, an IPPS-excluded hospital operating an IPPS-excluded unit must continue to be in compliance with other Medicare regulations and CoPs applicable to the hospital or unit. An IPPS-excluded unit within a hospital is part of the hospital. Noncompliance with any of the hospital CoPs at 42 CFR 482.1 through 482.58 at any part of a certified hospital is noncompliance for the entire Medicare-certified hospital. Therefore, noncompliance with the hospital CoPs in an IPPS excluded unit is CoP noncompliance for the entire certified hospital. For example, the CoPs that govern IPFs would apply to an IPF that operates an excluded rehabilitation unit, and those CoPs require that certain psychiatric treatment protocols apply to every IPF patient (including those in the rehabilitation unit).

We are proposing cost reporting periods beginning on or after October 1, 2019 would be the effective date of these changes to allow sufficient time for both CMS and IPPS-excluded hospitals to make the necessary administrative and operational changes to fully implement the proposed changes. We believe this proposed effective date would, to the best of our ability, ensure that these units can begin to operate without unnecessary administrative issues and delays.

D. 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

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, authorizes 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 is titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and is commonly known as the Frontier Community Health

Integration Project (FCHIP) demonstration.

The authorizing statute states 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 stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 requires that the demonstration be budget neutral. Specifically, this provision states 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 states 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, CMS 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. These CAHs are located in Montana, Nevada, and North Dakota, and they are participating in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065) and FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296). Eight CAHs are participating in the telehealth intervention, three CAHs are participating in the skilled nursing facility/nursing facility bed intervention, and two CAHs are participating in the ambulance services intervention. Each CAH is allowed to participate in more than one of the interventions. None of the selected CAHs are 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) and FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), we finalized a policy to address the budget neutrality requirement for the demonstration. As explained in the FY 2018 IPPS/LTCH PPS final rule, we based our selection of 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 and uncertainty associated with projected Medicare utilization and costs, we adopted 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 is 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 demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. As we estimated for the FY 2018 IPPS/LTCH PPS final rule, for this FY 2019 IPPS/LTCH PPS proposed rule, we estimate that the total impact of the payment recoupment would be no greater than 0.03 percent of CAHs' total Medicare payments within one fiscal year (that is, Medicare Part A and Part B). The final budget neutrality estimates for the FCHIP demonstration will be based on the demonstration period, which is August 1, 2016 through July 31, 2019.

The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. As stated in the FY 2018 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, beginning in CY 2020. The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations. Therefore, because any reduction to CAH payments in order to recoup excess costs under the demonstration will not begin until CY 2020, this policy will have no impact for any national payment system for FY 2019.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2019

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:

- Section 15004(a), which changed the moratorium on increasing the number of beds in existing LTCHs and LTCH satellite facilities. However, we note that this moratorium expired effective October 1, 2017.
- Section 15004(b), which specifies that, beginning in FY 2018, the estimated aggregate amount of HCO payments in a given year is equal to 99.6875 percent of the 8 percent estimated aggregate payments for standard Federal payment rate cases (that is, 7.975 percent) while requiring that we adjust the standard Federal payment rate each year to ensure budget neutrality for HCO payments as if estimated aggregate HCO payments

made for standard Federal payment rate discharges remained at 8 percent as done through our previous regulatory requirement. (We note these provisions do not apply with respect to the computation of the applicable site neutral payment rate under section 1886(m)(6) of the Act.)

- Section 15006, which amended sections 114(c)(1)(A) and (c)(2) of the MMSEA, which provided a statutory extension on the moratoria on the full implementation of the 25-percent threshold policy on LTCH PPS discharges for LTCHs governed under § 412.534, § 412.536, and § 412.538 based on the LTCH's cost reporting period beginning dates. In addition to the statutory moratorium, in the FY 2018 IPPS/LTCH PPS final rule, we also implemented a 1-year regulatory delay on the full implementation of the 25-percent threshold policy under § 412.538 (82 FR 38318 through 38320).

- Section 15007, which extends the exclusion of Medicare Advantage plans' and site neutral payment rate discharges from the calculation of the average length of stay for all LTCHs, for discharges occurring in any cost reporting period beginning on or after October 1, 2015.

- Section 15008, which changed the classification of certain hospitals. Specifically, section 15008 of Pub. L. 114–255 provided for the change in Medicare classification for ''subclause (II)'' LTCHs by redesignating such hospitals from section 1886(d)(1)(B)(iv)(II) of the Act to section 1886(d)(1)(B)(vi) of the Act, which is described earlier.

- Section 15009, which provides for a temporary exception to the site neutral payment rate for certain spinal cord specialty hospitals for discharges occurring in cost reporting periods beginning during FY 2018 and 2019 for LTCHs that meet specified statutory criteria to be excepted from the site neutral payment rate.

- Section 15010, which created a new temporary exception to the site neutral payment rate for certain severe wound discharges from certain LTCHs during such LTCHs' cost reporting periods beginning during FY 2018.

In this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to make 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.

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 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 (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to charge the beneficiary for services delivered on those uncovered days (§ 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 on beneficiaries whose 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, payment for discharges occurring in cost reporting periods beginning in FY 2016 or 2017) 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 2019

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 757 MS–DRG groupings. For FY 2019, there would be 761 MS–DRG groupings based on the proposed changes discussed in section II.F. of the preamble of this FY 2019 IPPS/LTCH PPS 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. We then 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 the proposed rule, we provide a general summary of our existing methodology for determining the proposed FY 2019 MS–LTC–DRG relative weights under the LTCH PPS.

In this proposed rule, in general, for FY 2019, we are proposing to continue to use our existing methodology to determine the proposed 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 would 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, in this FY 2019 IPPS/LTCH PPS proposed rule, for FY 2019, 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 2019, 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 group all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we account 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 make 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; and
- 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, by 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 FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.F.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 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 2019

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 FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2018, through September 30, 2019 (FY 2019), 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 2019 presented in this proposed rule are the same as the proposed MS–DRGs that are being used under the IPPS for FY 2019. In addition, because the MS–LTC–DRGs for FY 2019 are the same as the proposed MS–DRGs for FY 2019, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 36 as discussed in section II.F. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also would be applicable under the LTCH PPS for FY 2019.

3. Development of the Proposed FY 2019 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 more costly (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 2019

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38303 through 38304), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2018.

In this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to continue to use our current methodology to determine the proposed MS–LTC–DRG relative weights for FY 2019, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the proposed MS–LTC–DRGs, proposed low-volume and no-volume MS–LTC–DRGs, proposed adjustments for nonmonotonicity, the steps for calculating the proposed MS–LTC–DRG relative weights with a proposed 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 2019, and we discuss the effects of our proposals concerning the data used to determine the proposed FY 2019 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

In previous fiscal years, Table 13A—Composition of Low-Volume Quintiles for MS–LTC–DRGs (which was listed in section VI. of the Addendum to the proposed and final rules and available via the internet on the CMS website) listed the composition of the low-volume quintiles for MS–LTC–DRGs for the respective year, and Table 13B—No-Volume MS–LTC–DRG Crosswalk (also listed in section VI. of the Addendum to the proposed rule final rules and available via the internet on the CMS website) listed the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs). The information contained in Tables 13A and 13B is used in the development Table 11—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges, which contains 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) for the respective fiscal year (and also is listed in section VI. of the Addendum to the proposed and final rules and is available via the internet on the CMS website). Because the information contained in Tables 13A and 13B does not contain proposed payment rates or factors for the applicable payment year, we are proposing to generally provide the 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.hhs.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 Table 11, we believe that this proposed change in the presentation of the information contained in Tables 13A and 13B will make it easier for the public to navigate and find the relevant data and information used for the development of proposed payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years.

c. Data

For this proposed rule, consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2019, we obtained total charges from FY 2017 Medicare LTCH claims data from the December 2017 update of the FY 2017 MedPAR file, which are the best available data at this time, and we are proposing to use Version 36 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 36 of the GROUPER in establishing the FY 2019 MS–LTC–DRG relative weights in the final rule. To calculate the proposed FY 2019 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 2017 update of the FY 2017 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment

rate under § 412.522(b) had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2017 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 2017 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 proposed FY 2019 MS–LTC–DRG relative weights using our current methodology, we are not making any proposals regarding the identification 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 severe wound care discharges from certain LTCHs or for certain spinal cord specialty hospitals provided by sections 15009 and 15010 of Public Law 114–255, respectively, had our implementation of that law and the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we are using for this proposed rule meet the criteria to be excluded from the site neutral payment rate under those exceptions (or would have met the criteria for exclusion had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had the applicable statutes been in effect at the time of the discharge), such data do not include any discharges that would have been paid based on the LTCH PPS standard Federal payment rate under the provisions of sections 15009 and 15010 of Public Law 114–255, had the exception been in effect at the time of the discharge.

Furthermore, consistent with our historical methodology, we are excluding any claims in the resulting data set that were submitted by LTCHs that are 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 are excluding 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 proposed MS–LTC–DRG relative weights for FY 2019.

In summary, in general, we identified the claims data used in the development of the proposed FY 2019 MS–LTC–DRG relative weights in this proposed rule, as we are proposing, 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, except for discharges which would have been excluded from the site neutral payment under the temporary exception for certain severe wound care discharges from certain LTCHs and under the temporary exception for certain spinal cord specialty hospitals), as well as the claims data of 9 all-inclusive rate providers reported in the December 2017 update of the FY 2017 MedPAR file and any Medicare Advantage claims data. (We note that there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2017 update of the FY 2017 MedPAR file. However, had there been we would trim 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 proposed relative weights for FY 2019.

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 2019 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2019. 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 are proposing to 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 2019, 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. (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 is 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 the 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 below). For FY 2019, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2019 MS–LTC–DRG relative weights.

In determining the proposed FY 2019 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 proposed low-volume MS–LTC–DRGs, such that we group the proposed ''low-volume MS–LTC–DRGs'' (that is, proposed 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 proposed 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 proposed 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 2017 update of the FY 2017 MedPAR files), we identified 271 proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of proposed MS–LTC–DRGs was then divided into 1 of the proposed 5 low-volume quintiles, each containing at least 54 MS–LTC–DRGs (271/5 = 54 with a remainder of 1). We assigned the proposed low-volume MS–LTC–DRGs to specific proposed low-volume quintiles by sorting the proposed 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 proposed low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we would assign the first 54 (1st through 54th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 54 proposed MS–LTC–DRGs with the highest average charge cases would be assigned into Quintile 5. Because the average charge of the 216th proposed low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 215th proposed low-volume MS–LTC–DRG (assigned to Quintile 4) than to the average charge of the 217th proposed low-volume MS–LTC–DRG (assigned to Quintile 5), we assigned it to Quintile 4 (such that Quintile 4 contains 55 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This results in 4 of the 5 proposed low-volume quintiles containing 54 proposed MS–LTC–DRGs (Quintiles 1, 2, 3, and 5) and 1 proposed low-volume quintile containing 55 MS–LTC–DRGs (Quintile 4). As discussed earlier, for this proposed rule, we are proposing to provide the list of the proposed composition of the low-volume quintiles for MS–LTC–DRGs for FY 2019 (previously displayed in Table 13A, which was in previous fiscal years listed in section VI. of the Addendum to the respective proposed and final rules and available via the internet on the CMS website) in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.hhs.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 2019 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 proposed 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 2019 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2019 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2019 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 above) 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 FY 2019 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). 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 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (step 3 below), 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 2019 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 2019 MS–LTC–DRG relative weights, the value of many proposed 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 2019 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 2019 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 are 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 proposed calculation of the proposed FY 2019 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 2019 MS–LTC–DRG relative weights would lower the proposed FY 2019 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 2019 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2019 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculate 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 2019 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 2019 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 2017 update of the FY 2017 MedPAR file and, therefore, for which no charge data was available for these proposed MS–LTC–DRGs. Because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' proposed MS–LTC–DRGs, ''error'' proposed MS–LTC–DRGs, and proposed 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 his step of the proposed relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We are proposing to cross-walk each proposed no-volume MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a proposed relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' proposed MS–LTC–DRG was 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 761 proposed MS–LTC–DRGs for FY 2019, we identified 347 MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes the 8 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed below). We are proposing to assign proposed relative weights to each of the 347 no-volume proposed MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to 1 of the remaining 414 (761 − 347 = 414) proposed MS–LTC–DRGs for which we calculated proposed relative weights based on the trimmed applicable LTCH cases in the FY 2017 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 the proposed MS–LTC–DRGs to which we cross-walked 1 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 below 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 2017 update of the FY 2017 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 2018, 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.

We then 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 2019. 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 described in Steps 1 through 4 above) 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, is 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 2019. (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 proposing to provide 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 2019 (previously displayed in Table 13B, which was in previous fiscal years listed in section VI. of the Addendum to the respective proposed and final rules and available via the internet on the CMS website) in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.hhs.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 2019 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 2019 (which, as

previously stated, we are proposing to provide 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 2017 MedPAR file that we are proposing to use 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 0.8881 for FY 2019 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 MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the proposed relative weights in this proposed rule.

For FY 2019, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant 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); Pancreas Transplant (MS–LTC–DRG 010); and Kidney Transplant (MS–LTC–DRG 652). 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 eight 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.

As discussed in section VII.C. of the preamble of this proposed rule, section 51005 of the Bipartisan Budget Act of 2018 (Public Law 115–123) extended the transitional blended payment rate for site neutral payment rate cases for an additional 2 years (that is, discharges occurring in cost reporting periods beginning in FYs 2018 and 2019 will continue to be paid under the blended payment rate). Therefore, in this proposed rule, consistent with our practice in FYs 2016 through 2018, we are proposing to establish a proposed relative weight for FY 2019 equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: proposed MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); proposed MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); proposed MS–LTC–DRG 881 (Depressive Neuroses); proposed MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); proposed MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); proposed MS–LTC–DRG 885 (Psychoses); proposed MS–LTC–DRG 886 (Behavioral & Developmental Disorders); proposed MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); proposed MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); proposed MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); proposed MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); proposed MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); proposed MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and proposed MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs do not meet the criteria for exclusion from the site neutral payment rate. As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a proposed relative weight for the ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs would always be paid at the site neutral payment rate, and, therefore, those proposed MS–LTC–DRGs would never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, which was extended to include FYs 2018 and 2019 under Public Law 115–123. (We refer readers to section VII.C. of the preamble of this proposed rule for a detailed discussion of the extension of the transitional blended payment method provisions under Public Law 115–123 and our proposals for FY 2019. Under the transitional payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2018, and on or before September 30, 2019, site neutral payment rate cases are paid 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. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs in FY 2019, we assigned a proposed relative weight to these proposed MS–LTC–DRGs for FY 2019 that is the same as the FY 2018 relative weight (which is also the same as the FYs 2016 and 2017 relative weight). We believe that using the respective FY 2015 relative weight for each of the ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we are able to determine proposed relative weights based on applicable LTCH cases in the December 2017 update of the FY 2017 MedPAR file data using the steps

described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the proposed MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a proposed relative weight for those 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs to be used for the sole purposes of determining half of the transitional blended payment for site neutral payment rate cases during the transition period (80 FR 49631 through 49632) or payment for discharges from spinal cord specialty hospitals under § 412.522(b)(4).

In summary, for FY 2019, we are proposing to establish a proposed relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the proposed MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs listed previously (that is, proposed MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). 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, reflects this policy.

Step 6—Adjust the proposed FY 2019 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 2019 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 2018 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 2019 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 2019 based on the most recent available LTCH data for applicable LTCH cases, and continue to apply a budget neutrality adjustment in determining the proposed FY 2019 MS–LTC–DRG relative weights.

In this FY 2019 IPPS/LTCH PPS 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 2019, we grouped applicable LTCH cases using the proposed FY 2019 Version 36 GROUPER, and the recalibrated proposed FY 2019 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2018 GROUPER Version 35 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2018 by the average CMI for proposed FY 2019. 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 2019 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed FY 2019 normalized relative weights and proposed GROUPER Version 36; simulated estimated total FY 2018

LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2018 MS–LTC–DRG relative weights and the FY 2018 GROUPER Version 35; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2018 by the simulated estimated total LTCH PPS standard Federal payment rate payments for FY 2019. 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 proposed MS–LTC–DRG budget neutrality methodology, for FY 2019, 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 2019 (the first step of our proposed budget neutrality methodology), we used the following three steps: (1.a.) used the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2017 MedPAR file) and grouped them using the proposed FY 2019 GROUPER (that is, Version 36 for FY 2019) and the recalibrated proposed FY 2019 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) grouped the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2018 GROUPER (Version 35) and FY 2018 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) computed the ratio of these average case-mix indexes by dividing the average CMI for FY 2018 (determined in Step 1.b.) by the average case-mix index for FY 2019 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2019, each recalibrated proposed MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.27598 (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 proposed MS–LTC–DRG budget neutrality methodology, we calculate a second proposed budget neutrality factor consisting of the ratio of estimated aggregate FY 2019 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 2019 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 2019, under the second step of the proposed budget neutrality methodology, we are proposing to determine the proposed budget neutrality adjustment factor using the following three steps: (2.a.) simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed normalized relative weights for FY 2019 and GROUPER Version 35 (as described above); (2.b.) simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2018 GROUPER (Version 35) and the FY 2018 MS–LTC–DRG relative weights in Table 11 of the FY 2018 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculated 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 2019 MS–LTC–DRG relative weights, each normalized proposed relative weight is then multiplied by a budget neutrality factor of 0.992183 (the value determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2019 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.27598 and a budget neutrality factor of 0.992183. 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 2019.

C. Proposed Modifications to the Application of the Site Neutral Payment Rate (§ 412.522)

Section 1206 of Pathway for SGR Reform Act (Public Law 113–67) mandated the new dual rate payment system under the LTCH PPS beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. In addition, the statute established a transitional blended payment method for cases that would be paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. For those discharges, the applicable site neutral payment rate is the transitional blended payment rate specified in section 1886(m)(6)(B)(iii) of the Act. Section 1886(m)(6)(B)(iii) of the Act specifies that the transitional blended payment rate is comprised of 50 percent of the site neutral payment rate for the discharge under section 1886(m)(6)(B)(ii) of the Act and 50 percent of the LTCH PPS standard Federal payment rate that would have applied to the discharge if paragraph (6) of section 1886(m) of the Act had not been enacted.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49610 through 49612), we specified under § 412.522(c)(3), for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015, and on or before September 30, 2017 (that is, discharges occurring in cost reporting periods beginning during FYs 2016 and 2017),

that the payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate determined under § 412.523. In addition, we established that the payment amounts determined under § 412.522(c)(1) (the site neutral payment rate) and under § 412.523 (the LTCH PPS standard Federal rate) include any applicable adjustments, such as HCO payments, as applicable.

Section 51005 of the Bipartisan Budget Act of 2018 (Public Law 115–123) extended the transitional blended payment rate period for site neutral payment rate cases for 2 years, and provided for an adjustment to the payment for discharges paid under the site neutral payment rate through FY 2026. Specifically, section 51005(a) of Public Law 115–123 amended section 1886(m)(6)(B)(i) of the Act to extend the transitional blended payment rate for site neutral payment rate cases for an additional 2 years; that is, discharges occurring in cost reporting periods beginning in FYs 2018 and 2019 will continue to be paid under the blended payment rate. To codify the provisions of section 51005(a) of Public Law 115–123, we are proposing to revise our regulations at § 412.522(c)(3) to reflect the extension of the transitional blended payment rate period for discharges paid at the site neutral payment rate to include discharges occurring in cost reporting periods beginning on or before September 30, 2019.

In addition, as initially enacted, section 1886(m)(6)(B)(iii) of the Act specified that, for LTCH discharges occurring in cost reporting periods beginning during FY 2018 or later, the applicable site neutral payment rate would be the site neutral payment rate as defined in section 1886(m)(6)(B)(ii) of the Act. Section 51005(b) of Public Law 115–123 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined at section 1886(m)(6)(B)(ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026. In order to implement section 51005(b) of Public Law 115–123, we are proposing to revise § 412.522(c)(1) by adding new paragraph (iii) to specify that, for discharges occurring in FYs 2018 through 2026, the amount payable under § 412.522(c)(1)(i) (that is, the IPPS comparable amount) will be reduced by 4.6 percent.

We also are proposing to make a conforming amendment to § 412.500, which specifies the basis and scope of subpart O of 42 CFR part 412, by adding paragraph (a)(9) to reflect the provisions of section 51005 of the Bipartisan Budget Act of 2018.

D. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2019

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 412.538. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2019, that is, effective for LTCH discharges occurring on or after October 1, 2018 through September 30, 2019. 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 LTCHs 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 following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180); FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637); FY 2017 IPPS/LTCH PPS final rule (81 FR 57296 through 57310); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 58536 through 58547).

In this FY 2019 IPPS/LTCH PPS proposed rule, we present our proposals related to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2019.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2019 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 2019 are discussed below, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2019 as required by the statute (as discussed in section VII.E.2.c. of the preamble of this proposed rule). In addition, we are 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 adjustment for FY 2019 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).

2. Proposed FY 2019 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). 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 2019

CMS has used an estimated market basket increase to update the LTCH PPS. As noted above, we adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017. The 2013-based LTCH market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2013-based LTCH market basket, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57101 through 57102).) We continue to believe that the 2013-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57100). Therefore, in this proposed rule, we are proposing to use the 2013-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2019.

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 provides for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act.

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 2019

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 2017 forecast, the FY 2019 full market basket estimate for the LTCH PPS using the 2013-based LTCH market basket is 2.7 percent. The current estimate of the MFP adjustment for FY 2019 based on IGI's fourth quarter 2017 forecast is 0.8 percent.

For FY 2019, 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 2019 market basket increase by the proposed FY 2019 MFP adjustment. To determine the proposed market basket increase for LTCHs for FY 2019, as reduced by the proposed MFP adjustment, consistent with our established methodology, we are subtracting the proposed FY 2019 MFP adjustment from the estimated FY 2019 market basket increase. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate for FY 2019 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.75 percent for FY 2019. Therefore, following application of the proposed productivity adjustment, we are proposing to further reduce the proposed adjusted market basket update (that is, the proposed full FY 2019 market basket increase less the proposed MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP adjustment and the ''other adjustment'' required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2019, 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, the proposed update to the LTCH PPS standard Federal payment rate for FY 2019 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full LTCH PPS market basket increase estimate, subject to the MFP adjustment as required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, is also further reduced by 2.0 percentage points.

In this FY 2019 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2019 full market basket estimate of 2.7 percent (based on IGI's fourth quarter 2017 forecast of the 2013-based LTCH market basket) by the proposed FY 2019 MFP adjustment of 0.8 percentage point (based on IGI's fourth quarter 2017 forecast). Following application of the proposed MFP adjustment, we are proposing to reduce the proposed adjusted market basket update of 1.9 percent (2.7 percent minus 0.8 percentage point) by 0.75 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2019 of 1.15 percent (that is, the most recent estimate of the proposed LTCH PPS market basket increase of 2.7 percent, less the proposed MFP adjustment of 0.8 percentage point, and less the 0.75 percentage point required under section 1886(m)(4)(F) of the Act). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xv), which would specify that the LTCH PPS standard Federal payment rate for FY 2019 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS payment year updated by 1.15 percent, and as further adjusted, as appropriate, as described in § 412.523(d) (including the proposed budget neutrality adjustment for the proposed elimination of the 25-percent threshold policy under proposed § 412.523(d)(6) discussed in section VII.E. of the preamble of this proposed rule). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under proposed § 412.523(c)(3)(xv) in conjunction with § 412.523(c)(4), we are proposing to further reduce the proposed 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 an annual update to the LTCH PPS standard Federal payment rate of -0.85 percent (that is, 1.15 percent minus 2.0 percentage points) for FY 2019 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As stated earlier, consistent with our historical practice, we are proposing to use a more recent estimate of the market basket and the MFP adjustment to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2019 under § 412.523(c)(3)(xv) in the FY 2019 IPPS/LTCH PPS final rule. (We note that, consistent with historical practice, we also are proposing to adjust the proposed FY 2019 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 FY 2019 rule).)

E. Proposed Elimination of the ''25-Percent Threshold Policy'' Adjustment (§ 412.538)

The ''25-percent threshold policy'' is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25 percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are adjusted at cost report settlement (discharges not in excess of the threshold are unaffected by the 25-percent threshold policy). The 25-percent threshold policy was originally established in the FY 2005 IPPS final rule for LTCH HwHs and satellites (69 FR 49191 through 49214). We later expanded the 25-percent threshold policy in the RY 2008 LTCH PPS final rule to include all LTCHs and LTCH satellite facilities (72 FR 26919 through 26944). Several laws have mandated delayed implementation of the 25-percent threshold policy. For more details on the various laws that delayed the full implementation of the 25-percent threshold policy, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38318 through 38319).

In light of the further statutory delays and our continued consideration of public comments received in response to our proposal to consolidate and streamline the 25-percent threshold policy in the FY 2017 IPPS/LTCH PPS proposed rule, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38320), we adopted a 1-year regulatory moratorium on the implementation of the 25-percent threshold policy; that is, we imposed a regulatory moratorium on our implementation of the provisions of § 412.538 until October 1, 2018.

Since the introduction of the site neutral payment rate in FY 2016, many public commenters have asserted that the new site neutral payment rate would alleviate the policy concerns underlying the establishment of the 25-percent threshold policy. As we stated in our response to those comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57106) and in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38320), at that time, we were not convinced that this was the case. In addition, we received many public comments urging CMS to permanently rescind the 25-percent threshold policy in response to the Request for Information on CMS Flexibilities and Efficiencies that was included in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20159). These public comments also asserted that this policy is no longer necessary in light of the new dual payment rate system.

As discussed in the FY 2018 IPPS/LTCH PPS proposed and final rules (82 FR 20028 and 82 FR 38318 through 38319, respectively), the best available LTCH claims data at the time of the development of both rules (FY 2016 discharges) included many LTCH discharges that occurred during FY 2016 that were not yet subject to the site neutral payment rate because the statute provides that the site neutral payment rate be phased in, effective with LTCH cost reporting periods beginning on or after October 1, 2015 (that is, LTCH cost reporting periods beginning in FY 2016). Therefore, all FY 2016 discharges that occurred in a LTCH cost reporting period that began prior to October 1, 2016 were not subject to the site neutral payment rate.

Given these widespread concerns, the longstanding statutory delays, and the limited experience under the new dual rate payment system, we implemented the 1-year regulatory moratorium for FY 2018 to allow for the opportunity to do an analysis of LTCH admission practices under the new dual payment rate under the LTCH PPS based on more complete data. This implementation plan was, in part, intended to avoid confusion and expending unnecessary resources in implementation should our analysis ultimately conclude that the policy concerns underlying the 25-percent

threshold policy have been moderated (82 FR 38320).

Since establishing the current regulatory moratorium in the FY 2018 IPPS/LTCH PPS rulemaking, we have continued to receive additional communications seeking an end to our 25-percent threshold policy. We have considered these requests, along with reconsidering the many requests and public comments received through rulemaking, as we have reviewed our policies in the context of our ongoing initiative to reduce unnecessary regulatory burden. Our review also took note of the significant changes to LTCH admission practices and the LTCH PPS payment structure since the advent of the 25-percent threshold policy's adoption, such as the introduction of the site neutral payment rate beginning in FY 2016. One effect of these changes is the creation of a financial incentive for LTCHs to limit admissions according to the criteria for payment at the LTCH PPS standard Federal payment rate. While these changes do not specifically address our regulatory requirement to ensure that an LTCH does not act as an IPPS step-down unit, we believe that the creation of these financial incentives likely results in LTCH providers closely considering the appropriateness of admitting a potential transfer to an LTCH setting, regardless of the referral source, thereby lessening the concerns that led to the introduction of the 25-percent threshold policy.

In light of these factors, we recognize that the policy concerns that led to the 25-percent threshold policy may have been ameliorated, and that implementation of the 25-percent threshold policy would place a regulatory burden on providers. Therefore, we believe it is appropriate at this time to propose the removal of this payment adjustment policy. For these same reasons, we believe the specific regulatory framework of the 25-percent threshold policy at § 412.538 is no longer an appropriate mechanism to ensure that the statutory requirement that an LTCH does not act as a defacto unit of an IPPS hospital is not violated. Therefore, in this proposed rule, we are proposing to eliminate the 25-percent threshold policy under § 412.538.

The goal of our proposal to eliminate the 25-percent threshold policy is to reduce unnecessary regulatory burden. Independent of this goal, we continue to believe aggregate LTCH PPS payments are sufficient. Therefore, we do not believe that it would be appropriate to change the aggregate amount of LTCH PPS payments on a permanent basis. As described earlier, the 25-percent threshold policy would have reduced the LTCH PPS payments for certain discharges, and if finalized, this proposal to eliminate the 25-percent threshold policy would be expected to result in an increase in aggregate LTCH PPS payments. As a result, we believe that this proposal should be accomplished in a budget-neutral manner.

With respect to the issue about the adequacy of LTCH payment levels, we note that MedPAC, in each of its annual updates to Congress since 2011, has concluded that current LTCH PPS payment levels are appropriate, and thus has recommended since 2011 the elimination of the annual update to the LTCH payment rates. (For example, we refer readers to MedPAC's March 2011 ''Report to the Congress: Medicare Payment Policy,'' Chapter 10, page 246, and MedPAC's March 2018 ''Report to the Congress: Medicare Payment Policy,'' Chapter 11, page 315.) We believe application of this burden reduction-related proposal to eliminate the 25-percent threshold policy would result in an unwarranted increase in aggregate payment levels. Therefore, if we finalize our proposal to eliminate the 25-percent threshold policy, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we also are proposing to make a one-time, permanent adjustment to the proposed FY 2019 LTCH PPS standard Federal payment rate. That adjustment would be set such that our projection of aggregate LTCH payments in FY 2019 that would have been paid if the 25-percent threshold policy had gone into effect (that is, as if the 25-percent threshold policy under § 412.538 remained in effect during FY 2019) are equal to our projection of aggregate LTCH payments in FY 2019 payments for such cases in the absence of that policy.

To do this, we are proposing to remove the provisions of § 412.538, reserve this section, and add a new paragraph (d)(6) to § 412.523 to provide for a one-time permanent budget neutrality factor adjustment to the LTCH PPS standard Federal payment rate to ensure that removal of the 25-percent threshold policy at existing § 412.538 is budget neutral. (We note that, in the proposed § 412.523(d)(6), we refer to the 25-percent threshold policy as ''limitation on long-term care hospital admissions from referring hospitals'', which is the title of existing § 412.538.) In addition, we are proposing to make conforming technical changes to remove paragraph (c)(2)(v) of § 412.522 and paragraph (d)(6) of § 412.525.

Under this proposal, the budget neutrality adjustment would only be applied to the LTCH PPS standard Federal payment rate (or such portion of a blended payment) because payments made under the site neutral payment rate would be unaffected by the 25-percent threshold policy. (Discharges in excess of the 25-percent threshold policy would be paid the lesser of the applicable LTCH payment or an IPPS equivalent payment. The site neutral payment rate would remain set at the lesser of the IPPS comparable amount or cost, neither of which would exceed the IPPS equivalent payment amount.) However, because the applicable site neutral payment rate for all LTCHs during all of FY 2019 is based on the transitional blended payment rate (that is, 50 percent of the site neutral payment rate and 50 percent of the LTCH PPS standard Federal payment rate), any adjustment applied to the LTCH PPS standard Federal payment rate would also need to be applied to the LTCH PPS standard Federal rate portion of payments that affect site neutral payment rate cases.

Therefore, as noted earlier, we must account for the change in payments to both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases when determining the proposed budget neutrality adjustment. To do so, we are proposing to use the following methodology to determine the proposed budget neutrality factor that would be applied to the proposed FY 2019 LTCH PPS standard Federal payment rate using the best available LTCH claims data (the December 2017 update of the FY 2017 MedPAR files). Consistent with historical practice, if more recent data become available, we are proposing to use such data for the final rule.

Step 1—Simulate estimated aggregate FY 2019 LTCH PPS payments (that is, both LTCH PPS standard Federal payment rate payment cases and site neutral payment rate cases) without the 25-percent threshold policy at § 412.538.

Step 2—Estimate aggregate payments incorporating the payment reduction under the 25-percent threshold policy at § 412.538 as follows:

- *Step 2a*—Determine the applicable percentage threshold for each LTCH. In general, the applicable percentage threshold is 25 percent; however, the applicable percentage threshold is 50 percent for exclusively rural LTCHs, and LTCHs located in an MSA with an MSA-dominant hospital get an adjusted threshold (§ 412.538(e)). To determine the applicable percentage threshold for LTCHs located in an MSA with an MSA-dominant hospital, we used IPPS claims data from the March 2017 update

of the FY 2016 MedPAR files to determine, for each CBSA, the highest discharge percentage among all IPPS providers within that CBSA. (As discussed in section V. of the Addendum to this proposed rule, the CBSA-based geographic classifications currently used under the LTCH PPS are based on the OMB labor market area delineations based on the 2010 Decennial Census data (that is, are an MSA under § 412.503). The applicable percentage threshold for a given CBSA is this highest discharge percentage unless this percentage is higher than 50 percent or lower than 25 percent. In those cases, the threshold is 50 percent or 25 percent, respectively (§ 412.538(e)(3)).

- *Step 2b*—For each LTCH, determine the percentage of Medicare discharges admitted from any single referring IPPS hospital, consistent with § 412.538(d)(2). To do so, we used the March 2017 update of the FY 2016 MedPAR files to determine the total discharges for each LTCH and the number of applicable transfers from each referring IPPS hospital. The referring IPPS hospital's applicable transfers are the LTCH's Medicare discharges that were admitted from that single referring IPPS hospital where an outlier payment was not made to that referring hospital and for whom payment was not made by a Medicare Advantage plan. The ratio of the referring IPPS hospital's applicable transfers to the LTCH's total Medicare discharges, multiplied by 100, is the percentage of Medicare discharges admitted from any single referring IPPS hospital.
- *Step 2c*—Estimate the aggregate payment reduction under the 25-percent threshold policy:

(i) Determine the LTCH's discharges that are in excess of the applicable percentage threshold by comparing the LTCH's percentage of Medicare discharges admitted from each single referring IPPS hospital (Step 2b) to the LTCH's applicable percentage threshold (Step 2a).

(ii) Estimate the aggregate payment reduction under the 25-percent threshold policy for the Medicare discharges that caused the LTCH to exceed or remain in excess of the threshold by summing the difference between:

- The original LTCH PPS payment amount (that is, the otherwise applicable LTCH PPS payment without an adjustment under the 25-percent threshold policy); and
- The estimated adjusted payment amount under the 25-percent threshold policy. (We note that there is no payment adjustment under the 25-percent threshold policy for discharges that are not in excess of the LTCH's applicable percentage threshold.)

Step 3—Calculate the ratio of the estimated aggregate FY 2019 LTCH PPS payments with and without the estimated aggregate payment reduction under the 25-percent threshold policy to determine the adjustment factor that would need to be applied to the proposed FY 2019 LTCH PPS standard Federal payment rate to achieve budget neutrality (that is, the adjustment that would have to be applied to the proposed FY 2019 LTCH PPS standard Federal payment rate so that the estimated aggregate payments calculated in Step 1 are equal to the estimated aggregate payments with the reduction as calculated in Step 2). This ratio is calculated by dividing the estimated FY 2019 payments without incorporating the estimated aggregate payment reduction under the 25-percent threshold policy at § 412.538 (calculated in Step 1) by the estimated FY 2019 payments incorporating the estimated aggregate payment reduction under the 25-percent threshold policy at § 412.538 (calculated in Step 2). We note that, under Step 3, an iterative process is used to determine the adjustment factor that would need to be applied to the proposed FY 2019 LTCH PPS standard Federal payment rate to achieve budget neutrality because the portion of estimated FY 2019 payments that are not based on the LTCH PPS standard Federal payment rate (that is, the IPPS comparable amount portion under the SSO payment methodology and the site neutral payment rate portion of the transitional blended payment rate payment for site neutral payment rate discharges in FY 2019) are not affected by the application of budget neutrality factor.

We also note that, under this step, the proposed budget neutrality factor is applied to the proposed FY 2019 LTCH PPS standard Federal payment rate after the application of the proposed FY 2019 annual update and the proposed FY 2019 area wage level adjustment budget neutrality factor (discussed in section V. of the Addendum to this proposed rule).

Based on the FY 2017 LTCH claims data used for this proposed rule, we estimate that our proposed elimination of the 25-percent threshold policy would increase aggregate LTCH PPS payments by approximately $36 million. For this proposed rule, using the steps in the proposed methodology described above, we have determined a proposed budget neutrality factor for the proposed elimination of the 25-percent threshold policy of 0.990535. Accordingly, in section V. of the Addendum to this proposed rule, to determine the proposed FY 2019 LTCH PPS standard Federal payment rate, we are proposing to apply a one-time, permanent budget neutrality factor of 0.990535 for the proposed elimination of the 25-percent threshold policy. The proposed FY 2019 LTCH PPS standard Federal payment rate shown in Table 1E reflects this proposed adjustment.

As part of the reexamination and review of the 25-percent threshold policy described earlier, we also considered proposing an additional 1-year regulatory moratorium on the full implementation of the 25-percent threshold policy. Such a policy would also have resulted in an unwarranted increase in LTCH payments for the reasons discussed earlier, and for these same reasons we also would have proposed to implement such a moratorium in a budget neutral manner. We calculated the budget neutrality factor that would have had to be applied to address such increases during that 1-year delay in implementation using the proposed methodology outlined above (that is, a factor of 0.990535) to the LTCH PPS standard Federal payment rate for 1 year, FY 2019. Furthermore, under such a proposal, we would have proposed to modify § 412.538 by revising the effective date to apply to discharges occurring on or after October 1, 2019, and we would have proposed to amend § 412.523(d) to specify that the LTCH PPS standard Federal payment rate would be adjusted for FY 2019 by a factor that would ensure the 1-year delay in the implementation of the 25-percent threshold policy at § 412.538 for discharges occurring during FY 2019 would be budget neutral.

We are inviting public comments on our proposal to permanently eliminate the 25-percent threshold policy in a budget neutral manner, or, in the alternative, the adoption of an additional 1-year delay on the implementation of the policy with a budget neutrality adjustment. In addition, we are inviting public comments on whether the 25-percent threshold policy should be retained in FY 2019 and subsequent years.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we are proposing changes to 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 Program.

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).

We refer readers to section I.A.2. of the preamble of this proposed rule for a discussion of the Meaningful Measures Initiative.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. 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 health care 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 health care quality and value, while giving patients the tools and information needed to make the best decisions for them.

We seek to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely-agreed upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of 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), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348) for the measures we have adopted for the Hospital IQR Program measure set through the FY 2019 and FY 2020 payment determinations and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for chart-abstracted clinical process of care measures used in the Hospital IQR Program, or links to websites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Inpatient Quality Measures (Specifications Manual). This Specifications Manual is posted on the QualityNet website at: *http://www.qualitynet.org/*. We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required chart-abstracted clinical process of care measures.

The technical specifications for electronic clinical quality measures (eCQMs) used in the Hospital IQR Program are contained in the CMS Annual Update for Hospital Quality Reporting Programs (Annual Update). This Annual Update is posted on the Electronic Clinical Quality Improvement (eCQI) Resource Center web page at: *https://ecqi.healthit.gov/*. 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 EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs. We refer readers to section VIII.A.11.d.(1) of the preamble of this proposed rule in which we discuss the transition to Clinical Quality Language (CQL) beginning with the Annual Update that will be published in the spring of 2018 and for implementation in CY 2019.

In addition, we believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program.

We recognize that some changes made to measures undergoing maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. For substantive measure updates, after submission to the Measures Under Consideration list and evaluation by the Measure Applications Partnership (MAP), we will continue to use rulemaking to adopt those substantive measure updates for the Hospital IQR Program. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111) for additional discussion of the maintenance of technical specifications for quality measures for the Hospital IQR Program. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional details on the measure maintenance process.

We are not proposing any changes to our policies on the measure maintenance process in this proposed rule.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA 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* website, *http://www.medicare.gov/hospitalcompare* after a 30-day preview period (78 FR50776 through 50778).

Information is available to the public on the *Hospital Compare* website. *Hospital Compare* is an interactive web tool that assists beneficiaries and providers by providing information on hospital quality of care to those who need to select a hospital and to support quality improvement efforts. The Hospital IQR Program currently includes measures capturing performance data on many aspects of care provided in the acute inpatient hospital setting. For more information on measures reported to *Hospital Compare,* we refer readers to the

website at: *http://www.medicare.gov/hospitalcompare*.

Other information that may not be as relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations are not reported on the *Hospital Compare* website and may be made available on other CMS websites, such as *https://data.medicare.gov*. CMS also provides stakeholders access to archived data from the *Hospital Compare* website, which can be found at: *https://data.medicare.gov/data/archives/hospital-compare*. In this proposed rule, we are not proposing any changes to these policies.

We note that in section VIII.A.10. of the preamble of this proposed rule, we discuss our efforts to provide stratified data in hospital confidential feedback reports and potentially making stratified data publicly available on the *Hospital Compare* website in the future.

d. Meaningful Measures Initiative and the Hospital IQR Program

In this proposed rule, we are proposing a number of new policies for the Hospital IQR Program. We developed these proposals after conducting an overall review of the Program under our new ''Meaningful Measures Initiative,'' which is discussed in more detail in section I.A.2. of the preamble of this proposed rule. The proposals reflect our efforts to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable). They also reflect our efforts to improve the usefulness of the data that we publicly report in the Hospital IQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how providers are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website.

As part of this review, we have taken a holistic approach to evaluating the Hospital IQR Program's current measures in the context of the measures used in the other IPPS quality programs (that is, the Hospital Readmissions Reduction Program, the HAC Reduction Program, and the Hospital VBP Program). We view the value-based purchasing programs together as a collective set of hospital value-based programs. Specifically, we believe the goals of the three value-based purchasing programs (the Hospital VBP, Hospital Readmissions Reduction, and HAC Reduction Programs) and the measures used in these programs together cover the Meaningful Measures Initiative quality priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment of illness, and making care affordable—but that the programs should not add unnecessary complexity or costs associated with duplicative measures across programs.

The Hospital Readmissions Reduction Program focuses on care coordination measures, which address the quality priority of promoting effective communication and care coordination within the Meaningful Measures Initiative. The HAC Reduction Program focuses on patient safety measures, which address the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. As part of this holistic quality payment program strategy, we believe the Hospital VBP Program should focus on the measurement priorities not covered by the Hospital Readmissions Reduction Program or the HAC Reduction Program. The Hospital VBP Program would continue to focus on measures related to: (1) The clinical outcomes, such as mortality and complications (which address the Meaningful Measures Initiative quality priority of promoting effective treatment); (2) patient and caregiver experience, as measured using the HCAHPS Survey (which addresses the Meaningful Measures Initiative quality priority of strengthening person and family engagement as partners in their care); and (3) healthcare costs, as measured using the Medicare Spending Per Beneficiary (MSPB)—Hospital measure (which addresses the Meaningful Measures Initiative priority of making care affordable). As part of this larger quality program strategy, we believe the Hospital IQR Program should focus on measure topics not covered in the other programs' measures. Although new Hospital VBP measures will be selected from the measures specified under the Hospital IQR Program, the Hospital VBP Program measure set will no longer necessarily be a subset of the Hospital IQR Program measure set. As discussed in section I.A.2. of the preamble of this proposed rule, we are engaging in efforts aimed at evaluating and streamlining regulations with the goal to reduce unnecessary costs, increase efficiencies, and improve beneficiary experience. While there may be some overlap between the Hospital IQR Program measure set and the Hospital VBP measure set, allowing removal of duplicative measures from the Hospital IQR Program once they have been adopted into the Hospital VBP Program would further these goals. We believe this framework will allow hospitals and patients to continue to obtain meaningful information about hospital performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in these programs does not outweigh the benefits of improving beneficiary care.

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. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. In this proposed rule, we are not proposing any changes to this policy.

3. 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. In this proposed rule, we are not proposing any changes to these policies. We also refer readers to section I.A.2. of the preamble of this proposed rule, in which we describe the quality topics that we have identified as high impact measurement

areas that are relevant and meaningful to both patients and providers.

Furthermore, in selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP Program. Because measures adopted for the Hospital VBP Program must first have been adopted under the Hospital IQR Program and publicly reported on the *Hospital Compare* website for at least one year, these two programs are linked. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries.

4. Removal Factors for Hospital IQR Program Measures

a. Current Policy

We most recently updated our measure removal and retention factors in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643).[278] The previously adopted removal factors are:

- Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (that is, ''topped-out'' measures): statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤ 0.10.
- Factor 2. A measure does not align with the current clinical guidelines or practice.
- Factor 3. The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic).
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 7. It is not feasible to implement the measure specifications.

We are not proposing to modify any existing removal factors.

b. Proposed New Measure Removal Factor

We are proposing to adopt an additional factor to consider when evaluating measures for removal from the Hospital IQR Program measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the preamble of this proposed rule with respect to our new ''Meaningful Measures Initiative,'' we are engaging in efforts to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other quality programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track confidential feedback preview reports and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the Hospital IQR Program, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the Hospital IQR Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including payment determination data) are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the Hospital IQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal factor, ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' beginning with the effective date of the FY 2019 IPPS/LTCH PPS final rule. We refer readers to section VIII.A.5.b. of the preamble of this proposed rule, where we are proposing to remove a number of measures based on this proposed removal factor.

5. Proposed Removal of Hospital IQR Program Measures

We refer readers to section VIII.A.4. of the preamble of this proposed rule for a discussion of our current and proposed measure removal criteria. In this proposed rule, we are proposing to remove a total of 39 measures from the Hospital IQR Program across the FYs 2020, 2021, 2022, and 2023 payment

[278] As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) for more information on the additional factors we consider in removing quality measures and the factors we consider in order to retain measures. We note in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we clarified the criteria for determining when a measure is ''topped-out.''

determinations as further discussed below.

a. Proposed Removal of Measure—Removal Factor 4, Performance or Improvement on a Measure Does Not Result in Better Patient Outcomes: Hospital Survey on Patient Safety Culture

We are proposing to remove the Hospital Survey on Patient Safety Culture measure beginning with the CY 2018 reporting period/FY 2020 payment determination based on removal Factor 4, ''performance or improvement on a measure does not result in better patient outcomes.'' The Hospital Survey on Patient Safety Culture measure was adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49662 through 49664) for the FY 2018 payment determination and subsequent years, to allow us to assess whether and which patient safety culture surveys were being utilized by hospitals and the frequency of their use. In that rule, we stated our belief that this would be a time-limited measure that would assist us in assessing the feasibility of implementing a single survey on patient safety culture in the future (80 FR 49661). When we adopted the measure, we acknowledged that we had not yet determined for how many years we would keep the measure in the Hospital IQR Program (80 FR 49664). By design, this structural measure does not provide information on patient outcomes, because hospitals are asked only whether they administer a patient safety culture survey, and therefore, does not result in better patient outcomes, removal Factor 4.

Our data indicate that 98 percent of hospitals have reported they use some version of a patient safety culture survey; a large majority of hospitals (69.6 percent) that reported on the measure for the CY 2016 reporting period/FY 2018 payment determination use the AHRQ Surveys on Patient Safety Culture (SOPS).[279] While we are proposing to remove this measure, the data already collected would still help inform consideration of a potential future patient safety culture measure for the Hospital IQR Program. However, at this time, we believe that the burden of reporting this measure outweighs the benefits of continued data collection. Therefore, we are proposing to remove the Hospital Survey on Patient Safety Culture measure for the CY 2018 reporting period/FY 2020 payment determination (for which the data submission period is April 1, 2019 through May 15, 2019) and subsequent years.

We are inviting public comment on our proposal.

b. Proposed Removal of Measures—Proposed Removal Factor 8, the Costs Associated With a Measure Outweigh the Benefit of Its Continued Use in the Program

We are proposing to remove a number of measures under our proposed new removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, across the FYs 2020, 2021, 2022, and 2023 payment determinations. These proposals are presented by measure type: (1) Structural measure: safe surgery checklist use; (2) patient safety; (3) claims-based readmission; (4) claims-based mortality; (5) hip/knee complications; (6) Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158); (7) clinical episode-based payment; (8) chart-abstracted clinical process of care; and (9) eCQMs. These are discussed in detail below.

(1) Structural Measure: Safe Surgery Checklist Use

We refer readers to the FY 2013 IPPS/LTCH PPS final rule where we adopted the Safe Surgery Checklist Use measure (77 FR 53531 through 53533). We are proposing to remove the Safe Surgery Checklist Use measure beginning with the CY 2018 reporting period/FY 2020 payment determination under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We refer readers to section VIII.A.4.b. of the preamble of this proposed rule, where we acknowledge that costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, we believe it may be unnecessarily costly for health care providers to report a measure for which our analyses show that there is no meaningful difference in performance or there is little room for continued improvement.

Based on our review of reported data on this measure, there is no meaningful difference in performance or there is little room for continued improvement. Our analysis is captured by the table below:

Payment determination	Encounters	Number of hospitals	Rate	75th percentile	90th percentile	Truncated COV
FY 2017	CY 2015 Q1–Q4	3,201	0.961	100.00	100.00	0.201
FY 2018	CY 2016 Q1–Q4	3,195	0.968	100.00	100.00	0.181

Based on the analysis above, the national rate of ''Yes'' response for this measure is nearly 1.0, or 100 percent, nationwide, and has remained at this level for the last two years, such that there is no distinguishable difference in hospital performance between the 75th and 90th percentiles. In addition, the truncated coefficient of variation has decreased such that it is trending towards 0.10. Our analysis indicates that performance on this measure is trending towards topped-out status, that is to say, safe surgery checklists for surgical procedures are widely in use and there is little room for improvement on this structural measure.

In addition, we believe this measure is of more limited utility for internal hospital quality improvement efforts. This structural measure of hospital process determines whether a hospital utilizes a safe surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods. For the measure, hospitals indicate by ''Yes'' or ''No'' whether or not they use a safe surgery checklist for surgical procedures that includes safe surgery practices during each of the aforementioned perioperative periods. The measure does not require a hospital to report whether it uses a checklist in connection with each individual inpatient procedure.

Furthermore, removal of this measure would alleviate burden to hospitals associated with reporting on this measure. We anticipate a reduction in information collection burden because

[279] The Agency for Healthcare Research and Quality (AHRQ) sponsored the development of patient safety culture assessment tools for various healthcare organizations which assess patient safety culture in a health care setting. Patient safety culture is the extent to which an organization's culture supports and promotes patient safety. The survey tools are measured by what is rewarded, supported, and accepted, expected, and accepted in an organization as it relates to patient safety. (*https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/index.html*).

reporting on this measure takes hospitals approximately two minutes each year (77 FR 53666). As such, we believe the costs associated with reporting on this measure outweigh the associated benefits of keeping it in the Hospital IQR Program because it no longer meaningfully supports the Program objective of informing beneficiary choice since safe surgery checklists are widely in use.

Therefore, we are proposing to remove the Safe Surgery Checklist Use measure beginning with the CY 2018 reporting period/FY 2020 payment determination, for which the data submission period is April 1, 2019 through May 15, 2019, under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We also refer readers to the CY 2018 OPPS/ASC PPS final rule in which the Hospital OQR and ASCQR Programs finalized removal of the Safe Surgery Checklist Use measure beginning with the CY 2018 reporting period/CY 2020 payment determination for the Hospital OQR Program and with the CY 2019 payment determination for the ASCQR Program (82 FR 52363 through 52364; 82 FR 52571 through 52572; and 82 FR 52588 through 52589). We note that if the proposed removal Factor 8 is not finalized, removal of this measure would not be finalized.

We are inviting public comment on our proposal.

(2) Patient Safety Measures

We are proposing to remove the Patient Safety and Adverse Events Composite [280] (PSI 90) beginning with the CY 2018 reporting period/FY 2020 payment determination and five National Health and Safety Network (NHSN) hospital-acquired infection (HAI) measures beginning with the CY 2019 reporting period/FY 2021 payment determination under the proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

(a) Proposed Removal for CY 2018 Reporting Period/FY 2020 Payment Determination—Patient Safety and Adverse Events Composite (PSI 90) (NQF #0531) (Adopted at 73 FR 48602, Refined at 81 FR 57128 Through 57133)

We are proposing to remove PSI 90 beginning with the FY 2020 payment determination (which would use a performance period of July 1, 2016 through June 30, 2018). As PSI 90 is a claims-based measure, it uses claims and administrative data to calculate the measure without any additional data collection from hospitals. Thus, operationally, we would be able to remove the PSI 90 measure sooner than the NHSN HAI measures. Our reasons for proposing to remove this measure are discussed further below.

(b) Proposed Removals for the CY 2019 Reporting Period/FY 2021 Payment Determination

- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) (adopted at 76 FR 51630 through 51631);
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) (adopted at 76 FR 51616 through 51618);
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) (adopted at 75 FR 50200 through 50202);
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus Aureus* Bacteremia (MRSA) Outcome Measure (NQF # 1716) (adopted at 76 FR 51630); and
- American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753) (Colon and Abdominal Hysterectomy SSIs) (adopted at 75 FR 50200 through 50202).

We are proposing to remove the CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI measures from the Hospital IQR Program beginning with the CY 2019 reporting period/FY 2021 payment determination. These measures would remain in the Hospital IQR Program until that time, and their reporting would still be tied to FY 2019 and FY 2020 payment adjustments under the Hospital IQR Program. Although we are proposing to remove these measures from the Hospital IQR Program, we are not proposing to remove them from the HAC Reduction Program, and they will continue to be tied to the payment adjustment under that program (section IV.J.1. of the preamble of this proposed rule). After removal from the Hospital IQR Program, these measures would continue to be reported on the *Hospital Compare* website under the public reporting requirements of the HAC Reduction Program. We are proposing to remove these measures beginning with the FY 2021 payment determination because hospitals already would have collected and reported data for the first three quarters of the CY 2018 reporting period for the FY 2020 payment determination by the time of publication of the FY 2019 IPPS/LTCH PPS final rule. Removing these five NHSN HAI measures in the proposed timeline would allow us to use the data already reported by hospitals in the CY 2018 reporting period for purposes of the FY 2020 payment adjustment.

We are proposing to remove these six measures under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We believe that removing the PSI 90, CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures from one program would eliminate development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Hospitals currently review multiple feedback reports for the NHSN HAI measures from three different hospital quality programs that use three different reporting periods, which result in interpreting slightly different measure rates for the same measures (under the Hospital IQR Program, a rolling four quarters of data are used to update the *Hospital Compare* website;

[280] We note that measure stewardship of the recalibrated version of the Patient Safety and Adverse Events Composite (PSI 90) is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Patient Safety Indicators and Adverse Events Composite (CMS PSI 90) when it is used in CMS quality programs.

under the Hospital VBP Program, 1-year periods are used for each of the baseline period and the performance period; and under the HAC Reduction Program, a 2-year performance period is used). Beneficiaries may also find it confusing to see public reporting on the same measures in different programs. In addition, maintaining the specifications for the measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data result in costs to CMS.

We believe the costs as discussed above outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of these measures solely in the HAC Reduction Program. Although we are proposing to remove these six patient safety measures from the Hospital IQR Program, we continue to recognize that improving patient safety and reducing NHSN HAIs is an important quality area, and we still believe these measures provide significant data on patient safety outcomes during inpatient hospitalization. For these reasons, and as discussed below, we intend to continue to use these measures in the HAC Reduction Program. Unlike the Hospital IQR Program, performance data on measures maintained in the HAC Reduction Program are used both to assess the quality of care provided at a hospital and to calculate incentive payment adjustments for a given year of the Program based on performance. Also, the HAC Reduction Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the above measures which are already included in the HAC Reduction Program, sufficiently incentivizing performance improvement on these measures among participating hospitals. By keeping the measures in the HAC Reduction Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to these measures.

We believe that removing these measures from the Hospital IQR Program, while keeping them in the HAC Reduction Program, strikes an appropriate balance of benefits in driving improvement on patient safety and costs associated with retaining these measures in more than one program, while continuing to keep patient safety improvement and reducing NHSN HAIs as high priorities. We refer readers to section IV.J.1. of the preamble of this proposed rule where we discuss safety measures included in the HAC Reduction Program. As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We believe retaining these measures in the HAC Reduction Program addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care.[281] In addition, as discussed in section I.A.2. of the preamble of this proposed rule, we believe keeping these measures in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

Therefore, we are proposing to remove the: (1) PSI 90 measure for the FY 2020 payment determination (which applies to the performance period of July 1, 2016 through June 30, 2018) and subsequent years; and (2) CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI measures for the CY 2019 reporting period/FY 2021 payment determination and subsequent years. We refer readers to section IV.I.2.c.(2) of the preamble of this proposed rule, where we also are proposing to remove these same measures from the Hospital VBP Program. We note that if the proposed removal Factor 8 is not finalized, removal of this measure would not be finalized.

We are inviting public comment on our proposals.

(3) Claims-Based Readmission Measures

We are proposing to remove the following seven claims-based readmission measures beginning with the FY 2020 payment determination:

- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (READM–30–AMI) (adopted at 73 FR 68781);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (READM–30–CABG) (adopted at 79 FR 50220 through 50224);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (READM–30–COPD) (adopted at 78 FR 50790 through 50792);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (READM–30–HF) (adopted at 73 FR 48606);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) (READM–30–PN) (adopted at 73 FR 68780 through 68781);
- Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (READM–30–THA/TKA) (adopted at 77 FR 53519 through 53521); and
- 30-Day Risk-Standardized Readmission Rate Following Stroke Hospitalization (READM–30–STK) (adopted at 78 FR 50794 through 50798).

We are proposing to remove READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, and READM–30–THA/TKA under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. (The READM–30–STK measure is discussed further below.) We believe removing these measures from the Hospital IQR Program would eliminate costs associated with implementing and maintaining these measures for the program, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measures in different programs. In addition, maintaining the specifications

[281] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

for the measures, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs as described above outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of these measures solely in the Hospital Readmissions Reduction Program. We believe the benefit to beneficiaries of keeping this measure in the Hospital IQR Program is limited because the public would continue to receive measure information via another CMS quality program.

Because we continue to believe these measures provide important data on patient outcomes following inpatient hospitalization (addressing the Meaningful Measures Initiative quality priority of promoting effective communication and coordination of care), we will continue to use these measures in the Hospital Readmissions Reduction Program. By keeping the measures in the Hospital Readmissions Reduction Program, patients, hospitals, and the public would continue to receive information about the quality of care provided with respect to these measures.

Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital Readmissions Reduction Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital Readmissions Reduction Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the above measures which are already in the Hospital Readmissions Reduction Program, sufficiently incentivizing performance improvement on these measures among participating hospitals. As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing these measures from the Hospital IQR Program is the best way to achieve this. In addition, as discussed in section I.A.2. of the preamble of this proposed rule, we believe keeping these measures in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

Furthermore, we are proposing to remove the READM–30–STK measure under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. The READM–30–STK measure collects important hospital-level, risk-standardized readmission rates following inpatient hospitalizations for strokes (78 FR 50794). However, these data also are captured in the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) adopted into the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528), because that measure comprises a single summary score, derived from the results of different models for each of the following specialty cohorts: medicine; surgery/gynecology; cardiorespiratory; cardiovascular; and neurology (77 FR 53522). These cohorts cover conditions and procedures defined by the AHRQ CCS, which collapsed more than 17,000 different ICD–9–CM diagnoses and procedure codes into 285 clinically-coherent, mutually-exclusive condition categories and 231 mutually-exclusive procedure categories (77 FR 53525). Readmission rates following inpatient hospitalizations for strokes are captured in that information, specifically, the neurology cohort. We believe that the costs associated with interpreting the requirements for two measures with overlapping data points outweigh the benefit to beneficiaries of the additional information provided by this measure, because the measure data are already captured within another measure in the Hospital IQR Program. Also, maintaining the specifications for this measure, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. Thus, removing the READM–30–STK measure would help to reduce duplicative data and produce a more harmonized and streamlined measure set. As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing this measure from the Hospital IQR Program is the best way to do that.

We recognize, however, that including condition- and procedure-specific clinical quality measure data can provide hospitals with actionable feedback to better equip them to implement targeted improvements in comparison to an overall quality measure. In addition, condition- and procedure-specific measures can provide valuable data to specialty societies by clearly assessing performance for their specialty, and may be valuable to persons and families who prefer information on certain conditions and procedures relevant to them. The Hospital-Wide Readmission measure, unlike condition- and procedure-specific measures, also requires improvement in quality across multiple service lines to produce improvement in the overall rate, which may give the perception of slower or smaller gains in hospital quality. Conversely, hospitals would still have a strong motivation to improve stroke readmissions performance if they want to improve their overall performance on the Hospital-Wide Readmission measure posted on *Hospital Compare.*

Therefore, we are proposing to remove the READM–30–AMI, READM–30–CABG, READM–30–COPD, READM–30–HF, READM–30–PN, READM–30–THA/TKA, and READM–30–STK measures for the FY 2020 payment determination (which would apply to the performance period of July 1, 2015 through June 30, 2018) and subsequent years. We note that if the proposed removal Factor 8 is not finalized, removal of these measures would not be finalized.

We are inviting public comment on our proposal to remove these measures from the Hospital IQR Program as well as feedback on whether there are reasons to retain one or more of the measures in the Hospital IQR Program.

(4) Claims-Based Mortality Measures

We are proposing to remove five claims-based mortality measures across the FYs 2020, 2021, and 2022 payment determinations and subsequent years:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230) (MORT–30–AMI) beginning with the FY 2020 payment determination (adopted at 71 FR 68206);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization Surgery (NQF #0229) (MORT–30–HF) beginning with the FY 2020 payment determination (adopted at 71 FR 68206);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) (NQF #1893) (MORT–30–COPD) beginning with the FY 2021 payment determination (adopted at 78 FR 50792 through 50794);

• Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468) (MORT–30–PN) beginning with the FY 2021 payment determination (adopted at 72 FR 47351); and,

• Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (MORT–30–CABG) beginning with the FY 2022 payment determination (adopted at 79 FR 50224 through 50227).

We are proposing to remove MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–PN, and MORT–30–CABG under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. Removing these measures from the Hospital IQR Program would eliminate costs associated with implementing and maintaining these measures for the program, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals for both the Hospital IQR and Hospital VBP Programs. We refer readers to section VIII.A.4.b. of this proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measures using different reporting periods in different programs. In addition, maintaining the specifications for the measures, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs associated with reviewing multiple feedback reports on these measures for more than one program outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of these measures solely in the Hospital VBP Program.

We continue to believe these measures provide important data on patient outcomes following inpatient hospitalization (addressing the Meaningful Measures Initiative quality priority of promoting effective communication and coordination of care), which is why we will continue to use these measures in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the above listed measures, sufficiently incentivizing performance improvement on these measures among participating hospitals. By keeping the measures in the Hospital VBP Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to these measures.

As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing incentivize improvement in the quality of care provided to patients, and we believe removing these measures from the Hospital IQR Program is the best way to achieve that goal. In addition, as discussed in section I.A.2. of the preamble of this proposed rule, we believe keeping these measures in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

We note that the Hospital VBP Program has adopted the MORT–30–COPD measure beginning with the FY 2021 program year (80 FR 49558), the MORT–30–PN measure (modified with the expanded cohort) beginning with the FY 2021 program year (81 FR 56996), and the MORT–30–CABG measure beginning with the FY 2022 program year (81 FR 56998). Therefore, we are proposing to stagger the beginning date of the removals of these measures from the Hospital IQR Program to avoid a gap in public reporting of measure data. For the Hospital IQR Program, we are proposing to remove the: (1) MORT–30–AMI and MORT–30–HF measures for the FY 2020 payment determination (which would use a performance period of July 1, 2015 through June 30, 2018) and subsequent years; (2) MORT–30–COPD and MORT–30–PN measures for the FY 2021 payment determination (which would use a performance period of July 1, 2016 through June 30, 2019) and subsequent years; and (3) MORT–30–CABG measure for the FY 2022 payment determination (which would use a performance period of July 1, 2017 through June 30, 2020) and subsequent years. We note that if the proposed removal Factor 8 is not finalized, removal of these measures would not be finalized.

We are inviting public comment on our proposal.

(5) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications) Measure

We are proposing to remove one complications measure, Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications), beginning with the FY 2023 payment determination, under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We refer readers to FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53518), where we adopted this measure.

We believe that removing this measure from the Hospital IQR Program would eliminate costs associated with implementing and maintaining the measure for the program, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on this measure as we also use the measure in the Hospital VBP Program and the Comprehensive Care for Joint Replacement model (CJR model). Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measure in different programs. In addition, maintaining the specifications for the measure, as well as the tools we need to

analyze and publicly report the measure data result in cost to CMS. We believe the costs as discussed above outweigh the associated benefit to beneficiaries of receiving the same information from more than one program, because that information can be captured through inclusion of this measure in the Hospital VBP Program.

As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing this measure from the Hospital IQR Program is the best way to achieve this goal. We believe retaining the Hip/Knee Complications measure in both the Hospital IQR Program and the Hospital VBP Program no longer aligns with our current goal of not adding unnecessary complexity or cost with duplicative measures across programs, as stated in section I.A.2. of the preamble of this proposed rule.

We continue to believe this measure provides important data on patient outcomes following inpatient hospitalization (addressing the Meaningful Measures Initiative quality priority of promoting effective treatment), which is why we will continue to use this measure in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the Hip/Knee Complications measure, sufficiently incentivizing performance improvement on this measure among participating hospitals. By keeping the measure in the Hospital VBP Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to this measure.

Therefore, we are proposing to remove the Hip/Knee Complications measure from the Hospital IQR Program beginning with the FY 2023 payment determination (which applies to the performance period of April 1, 2018 through March 31, 2021) and subsequent years. We chose to propose this timeframe because the Comprehensive Care for Joint Replacement model (CJR model) previously adopted the same measure and requires use of data collected under the Hospital IQR Program through the FY 2022 payment determination (which would use a performance period of April 1, 2017 through March 31, 2020) (80 FR 73507). After removal from the Hospital IQR Program, we note that this measure would continue to be reported on the *Hospital Compare* website under the public reporting requirements of the Hospital VBP Program. In addition, if the proposed removal Factor 8 is not finalized, removal of this measure would not be finalized.

We are inviting public comment on our proposal.

(6) Medicare Spending Per Beneficiary (MSPB)—Hospital Measure (NQF #2158) (MSPB)

We are proposing to remove one resource use measure, Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158) (MSPB), from the Hospital IQR Program beginning with the FY 2020 payment determination, under the proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51619) where we adopted this measure.

We believe that removing this measure from the Hospital IQR Program would eliminate costs associated with implementing and maintaining the measure, and in particular, development and release of duplicative and potentially confusing CMS confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. We refer readers to section VIII.A.4.b. of the preamble of this proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on this measure as we use the measure in the Hospital VBP Program. Health care providers incur additional cost to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Beneficiaries may also find it confusing to see public reporting on the same measure in different programs. In addition, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs as discussed above outweigh the associated benefit to beneficiaries of receiving the same information from multiple programs, because that information can be captured through inclusion of this measure solely in the Hospital VBP Program.

As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe removing this measure from the Hospital IQR Program helps achieve that goal. In addition, as discussed in section I.A.2. of the preamble of this proposed rule, we believe keeping this measure in both programs no longer aligns with our goal of not adding unnecessary complexity or cost with duplicative measures across programs.

We continue to believe this measure provides important data on resource use (addressing the Meaningful Measures Initiative priority of making care affordable), which is why we will continue to use this measure in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the MSPB measure, sufficiently incentivizing performance improvement on this measure among participating hospitals. By keeping the measure in the Hospital VBP Program, patients, hospitals, and the public continue to receive information about the quality of care provided with respect to these measures.

Therefore, we are proposing to remove the MSPB measure from the Hospital IQR Program beginning with the FY 2020 payment determination (which applies to the performance period of January 1, 2018 through December 31, 2018) and subsequent years. As a claims-based measure, which uses claims and administrative data to calculate the measure without any additional data collection from hospitals, we can operationally remove the MSPB measure sooner than certain

other measures we are proposing for removal in this proposed rule. We note that if proposed removal Factor 8 is not finalized, removal of this measure would not be finalized.

We are inviting public comment on our proposal.

(7) Clinical Episode-Based Payment Measures

We are proposing to remove six clinical episode-based payment measures from the Hospital IQR Program beginning with the FY 2020 payment determination:

- Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment) (adopted at 80 FR 49664 through 49674);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment) (adopted at 80 FR 49664 through 49674);
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment) (adopted at 80 FR 49664 through 49674);
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment) (adopted at 81 FR 57133 through 57142);
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment) (adopted at 81 FR 57133 through 57142); and
- Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment) (adopted at 81 FR 57133 through 57142).

We are proposing to remove the Cellulitis Payment, GI Payment, Kidney/UTI Payment, AA Payment, Chole and CDE Payment, and SFusion Payment measures under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We refer readers to section VIII.A.4.b. of the preamble of this proposed rule where we discuss examples of the costs associated with implementing and maintaining these measures for the programs. Specifically, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data result in costs to CMS. We believe the costs associated with interpreting the requirements for multiple measures with overlapping data points outweigh the benefit to beneficiaries and providers of the additional information provided by these measures, because the measure data are already captured within the overall hospital MSPB measure, which will be retained in the Hospital VBP Program.

These measures are clinically coherent groupings of health care services that can be used to assess providers' resource use associated with the clinically coherent groupings (80 FR 49664). Specifically, these measures all use Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for a clinical issue associated with the respective clinical groupings (80 FR 49664 through 49668; 81 FR 57133 through 57140). However, these data also are captured in the MSPB measure, which uses claims data for hospital discharges, including Medicare Part A and Part B payments for services rendered to Medicare beneficiaries during the Medicare spending per beneficiary episode surrounding an index hospitalization (76 FR 51618 through 51627). Although the MSPB measure does not provide the same level of granularity that these individual measures do, the most essential data elements will be captured by and publicly reported under the MSPB measure in the Hospital VBP Program. We understand that some hospitals may appreciate receiving more granular payment measure data from individual episode-based payment measures, while other hospitals may not benefit from the use of individual measures in addition to MSPB because they do not have a sufficient number of cases for those measures to be calculated. We are proposing to remove these measures because we believe that in balancing the costs of keeping these measures in the program compared to the benefit, providers would prefer to focus their improvement efforts on total payment, rather than both total payment and the payments associated with these individual types of clinical episodes. While we are proposing to remove the MSPB measure from the Hospital IQR Program as discussed in the section above, the measure would continue to be included in the Hospital VBP Program (section IV.I.2.e. of the preamble of this proposed rule). We also note that the Hospital IQR Program will retain certain condition- and procedure-specific payment measures (specifically, focusing on patients hospitalized for heart failure, AMI, pneumonia, and elective hip and/or knee replacement procedures) with readmissions and mortality measure data for the same patient cohorts. Since the MSPB measure would still be reported for the Hospital VBP Program, patients, hospitals, and the public would continue to receive information about the data provided by these resource measures. Thus, removing these six measures from the Hospital IQR Program would help to reduce duplicative data and produce a more harmonized and streamlined measure set. Further, and as explained above, the Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the MSPB measure, sufficiently incentivizing performance improvement on this measure among participating hospitals.

As discussed in section VIII.A.4.b. of the preamble of this proposed rule, above, one of our main goals is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, and we believe that removing these measures from the Hospital IQR Program helps achieve that goal. We recognize, however, that including specific episode-based payment measure data can provide hospitals with actionable feedback to better equip them to implement targeted improvements in comparison to an overall payment measure. In addition, these measures were only recently implemented in the Hospital IQR Program in the FY 2017 IPPS/LTCH PPS final rule and data have not yet become publicly available on the *Hospital Compare* website. However, because these episode-based payment measures are not tied directly with other clinical quality measures that could contribute to the overall picture of providers' clinical effectiveness and efficiency, we believe that the data derived from these measures may be of lower utility to patients in deciding where to seek care, as well as to providers in gaining feedback to reduce cost and improve efficiency while maintaining high quality care; they address resource use which is not directly tied to clinical quality, unless combined with other clinical quality measures (81 FR 57133 through 57134).

Therefore, we are proposing to remove the Cellulitis Payment, GI Payment, Kidney/UTI Payment, AA Payment, Chole and CDE Payment, and SFusion Payment measures for the FY 2020 payment determination (which applies to the performance period of January 1, 2018 through December 31, 2018) and subsequent years. Because these are claims-based measures, operationally, we are able to remove them sooner than certain other measures we are proposing for removal in this proposed rule. We note that if the proposed removal Factor 8 is not

finalized, removal of these measures would not be finalized.

We are inviting public comment on our proposal to remove these measures from the Hospital IQR Program as well as feedback on whether there are reasons to retain one or more of the measures in the Hospital IQR Program.

(8) Chart-Abstracted Clinical Process of Care Measures

In this proposed rule, we are proposing to remove the Influenza Immunization, Incidence of Potentially Preventable Venous Thromboembolism, Median Time from ED Arrival to ED Departure for Admitted ED Patients, and Admit Decision Time to ED Departure Time for Admitted Patients measures as discussed in detail below. Manual abstraction of these chart-abstracted measures is highly burdensome. We have previously stated our intent to move away from chart-abstracted measures in order to reduce this information collection burden (78 FR 50808; 79 FR 50242; 80 FR 49693). We refer readers to our discussion below and to section XIV.B.3.b. of the preamble of this proposed rule, where we discuss the information collection burden associated with each of these measures with greater specificity.

(a) Influenza Immunization Measure (NQF #1659) (IMM–2)

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50211) where we adopted the Influenza Immunization measure (NQF #1659) (IMM–2). In this proposed rule, we are proposing to remove IMM–2 beginning with the CY 2019 reporting period/FY 2021 payment determination under removal Factor 1—topped-out measure and under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

Hospital performance on IMM–2 is statistically ''topped-out''—removal Factor 1. The Hospital IQR Program previously finalized two criteria for determining when a measure is ''topped out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 50203). Our analysis indicates that performance on this measure has been topped-out for the past three payment determination years and also for Q1 and Q2 of 2017 encounters. This analysis is captured by the table below:

Payment determination	Encounters	Number of hospitals	Mean	75th percentile	90th percentile	Truncated COV
FY 2016	2014 (Q1–Q4)	3326	0.9292	0.9867	0.9965	0.0560
FY 2017	2015 (Q1–Q4)	3293	0.9372	0.9890	0.9970	0.0494
FY 2018	2016 (Q1–Q4)	3258	0.9370	0.9890	0.9970	0.0500

Our topped-out analysis shows that administration of the influenza vaccination to admitted patients is widely in practice and there is little room for improvement. We believe that hospitals will continue this practice even after the measure is removed; thus, utility in the program is limited.

Moreover, we are proposing to remove this measure under proposed removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program. We believe the information collection burden associated with manual chart abstraction, as discussed above, outweighs the associated benefit to beneficiaries of receiving this information, because: (1) It is topped out and there is little room for improvement (discussed above); and (2) it does not directly measure patient outcomes.

As discussed in section I.A.2. of the preamble of this proposed rule, one of the goals of the Meaningful Measures Initiative is to reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. Another goal of the Meaningful Measures Initiative is to utilize measures that are ''outcome-based where possible.'' IMM–2 is a process measure that tracks patients assessed and given an influenza vaccination with their consent, but does not directly measure patient outcomes.

We recognize and agree that influenza prevention is an important public health issue. We note that the Influenza Vaccination Coverage Among Healthcare Personnel (HCP) measure (adopted at 76 FR 51631 through 51633), which assesses the percentage of healthcare personnel at a facility who receive the influenza vaccination, remains in the Hospital IQR Program. Although the HCP measure is focused on vaccination of providers and other hospital personnel and not beneficiaries, it promotes improved health outcomes among beneficiaries because: (1) Health care personnel that have received the influenza vaccination are less likely to transmit influenza to patients under their care; and (2) vaccination of health care personnel reduces the probability that hospitals may experience staffing shortages as a result of illness that would impact ability to provide adequate patient care. Thus, we believe the costs associated with reporting this chart-abstracted measure outweighs the associated benefits of keeping it in the Hospital IQR Program.

We are proposing to remove the IMM–2 measure beginning with the CY 2019 reporting period/FY 2021 payment determination (which applies to the performance period of January 1, 2019 through December 31, 2019) because hospitals already would have collected and reported data for the first three quarters of the CY 2018 reporting period for the FY 2020 payment determination by the time of publication of the FY 2019 IPPS/LTCH PPS final rule. In addition, there are operational limitations associated with updating CMS systems in time to remove this measure sooner for the CY 2018 reporting period/FY 2020 payment determination. This proposed timeline (that is, beginning with the CY 2019 reporting period/FY 2021 payment determination) would subsequently allow us to use the data already reported by hospitals in the CY 2018 reporting period for public reporting on our *Hospital Compare* website and for data validation.

Therefore, we are proposing to remove the IMM–2 measure from the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination and subsequent years.

We are inviting public comment on our proposal.

(b) Incidence of Potentially Preventable Venous Thromboembolism Measure (VTE–6); Median Time From ED Arrival to ED Departure for Admitted ED Patients Measure (NQF #0495) (ED–1); and Admit Decision Time to ED Departure Time for Admitted Patients Measure (NQF #0497) (ED–2)

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51634 through 51636), where we adopted the Incidence of Potentially Preventable Venous Thromboembolism measure

(VTE–6), and to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50210 through 50211), where we adopted both the chart-abstracted version of the Median Time from ED Arrival to ED Departure for Admitted ED Patients measure (NQF #0495) (ED–1) and the Admit Decision Time to ED Departure Time for Admitted Patients measure (NQF #0497) (ED–2). In this proposed rule, we are proposing to remove VTE–6 and the chart-abstracted version of ED–1 beginning with the CY 2019 reporting period/FY 2021 payment determination; in addition, we are proposing to remove the chart-abstracted version of ED–2 beginning with the CY 2020 reporting period/FY 2022 payment determination. We are proposing to remove these three measures under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As discussed in section I.A.2. of the preamble of this proposed rule, one of the goals of our Meaningful Measures Initiative is to reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. We believe the information collection burden associated with manual chart abstraction, as discussed above, outweighs the associated benefit to beneficiaries of receiving information provided by these measures because much of the information provided by these measures is available through other Program measure data (as further discussed below).

Furthermore, in the case of ED–2, hospitals still would have the opportunity to submit data since the eCQM version will remain part of the Hospital IQR Program measure set. We note that in section VIII.A.5.b.(9)(c) of the preamble of this proposed rule, below, we are proposing to remove the eCQM version of ED–1, but to retain the eCQM version of ED–2 due to the continued importance of assessing ED wait times for admitted patients. Although ED–1 is an important metric for patients, ED–2 has greater clinical significance for quality improvement because it provides more actionable information such that hospitals have greater ability to allocate resources to consistently reduce the time between decision to admit and time of inpatient admission. Hospitals have somewhat less control to consistently reduce wait time between ED arrival and decision to admit, as measured by ED–1, due to the need to triage and prioritize more complex or urgent patients. Also, the Hospital OQR Program includes an ED throughput measure, OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (81 FR 79755), which publicly reports similar data as captured by ED–1. Therefore, we believe the costs to providers for submitting data on the chart-abstracted ED–1 and ED–2 measures outweigh the associated benefits of keeping the measures in the program given that other measures in the Hospital IQR Program and in other CMS hospital quality programs are able to capture actionable data on ED wait times.

Furthermore, although the eCQM version of VTE–6 is not included in the Hospital IQR Program, hospitals still would have the opportunity to submit data for two other VTE related measures (eCQMs), which were already adopted in the Hospital IQR Program measure set—Venous Thromboembolism Prophylaxis (VTE–1) (NQF #0371) eCQM (adopted at 78 FR 50809) and Intensive Care Unit Venous Thromboembolism Prophylaxis (VTE–2) (NQF #0372) eCQM (adopted at 78 FR 50809). The VTE–1 eCQM assesses the number of patients who received venous thromboembolism (VTE) prophylaxis or have documentation why no VTE prophylaxis was given the day of or day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission; the VTE–2 eCQM assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given on the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). The VTE–1 and VTE–2 measures will be retained in the Hospital IQR Program to encourage best clinical practices to those patients in this high risk population by providing prophylactic steps which will decrease the incidence of preventable VTE. In contrast, the VTE–6 measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. While awareness of the occurrence of preventable VTE is valuable knowledge, the prevention of the initial occurrence is more actionable and meaningful for both providers and beneficiaries. Therefore, we believe the costs to providers of submitting data on this chart-abstracted measure outweigh its limited clinical utility given other VTE measures in the Program are able to capture more actionable data on VTE.

As discussed in section VIII.A.4.b. of the preamble of this proposed rule, one of our main goals is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Therefore, we believe removing the chart-abstracted versions of the VTE–6, ED–1, and ED–2 measures from the Hospital IQR Program measure set helps achieve that goal.

We are proposing to remove the VTE–6 measure and chart-abstracted version of the ED–1 measure beginning with the CY 2019 reporting period/FY 2021 payment determination, because hospitals already would have collected and reported data for the first three quarters of the CY 2018 reporting period for the FY 2020 payment determination by the time of publication of the FY 2019 IPPS/LTCH PPS final rule. Moreover, we would not be able to overcome operational limitations associated with updating our systems in time to support removal of the VTE–6 and chart-abstracted version of the ED–1 measures for the CY 2018 reporting period/FY 2020 payment determination. In addition, we are proposing to remove the chart-abstracted version of the ED–2 measure beginning with the CY 2020 reporting period/FY 2022 payment determination, because the first results from validation of ED–2 eCQM data will be available beginning with the FY 2021 payment determination. We believe it is important to keep the chart-abstracted version of ED–2 in the program until after the validated data from the eCQM version of ED–2 is available for comparative analysis to evaluate the accuracy and completeness of the eCQM data. Further, removing these three measures on the proposed timelines would allow us to use the data already reported by hospitals in the CY 2018 reporting period for public reporting on our *Hospital Compare* website and for data validation.

Therefore, we are proposing to remove: (1) VTE–6 and the chart-abstracted version of ED–1 beginning with the CY 2019 reporting period/FY 2021 payment determination; and (2) the chart-abstracted version of ED–2 beginning with the CY 2020 reporting period/FY 2022 payment determination. We note that if the proposed removal Factor 8 is not finalized, removal of these measures would not be finalized.

We are inviting public comment on our proposals.

(9) Proposed Removal of Electronic Clinical Quality Measures (eCQMs)

In alignment with the Medicare and Medicaid Promoting Interoperability

Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and CAHs, we are proposing to reduce the number of electronic Clinical Quality Measures (eCQMs) in the Hospital IQR Program eCQM measure set from which hospitals must select four to report, by proposing to remove seven eCQMs (of the 15 measures currently in the measure set) beginning with the CY 2020 reporting period/FY 2022 payment determination. The seven eCQMs we are proposing to remove are:

- Primary PCI Received Within 90 Minutes of Hospital Arrival (AMI–8a) (adopted at 79 FR 50246);
- Home Management Plan of Care Document Given to Patient/Caregiver (CAC–3) (adopted at 79 FR 50243 through 50244);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED–1) (adopted at 78 FR 50807 through 50710);
- Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI–1a) (adopted at 79 FR 50242);
- Elective Delivery (NQF #0469) (PC–01) (adopted at 78 FR 50807 through 50810);
- Stroke Education (STK–08) (adopted at 78 FR 50807 through 50810); and,
- Assessed for Rehabilitation (NQF #0441) (STK–10) (adopted at 78 FR 50807 through 50810).

We are proposing to remove all seven eCQMs under proposed removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. As discussed in section I.A.2. of the preamble of this proposed rule, two of the goals of our Meaningful Measures Initiative are to: (1) Reduce costs associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology; and (2) to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. In section VIII.A.11.d.(2) of the preamble of this proposed rule, for the CY 2019 reporting period/FY 2021 payment determination, we are proposing to extend the same eCQM reporting requirements finalized for the CY 2018 reporting period/FY 2020 payment determination, such that hospitals submit one, self-selected calendar quarter of data on four self-selected eCQMs. Thus, we anticipate the collection of information burden associated with eCQM data reporting for the CY 2019 reporting period/FY 2021 payment determination will be the same as for the CY 2018 reporting period/FY 2020 payment determination. However, in section VIII.A.4.b. of the preamble of this proposed rule, we discuss our belief that costs associated with program requirements are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the measures for the Program, such as staying current on clinical guidelines and maintaining measure specifications in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program. With respect to eCQMs, we believe that a coordinated reduction in the overall number of eCQMs in both the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) would reduce costs and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs, while still allowing hospitals some flexibility to select which eCQMs to report that best reflect their patient populations and support internal quality improvement efforts. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57116 through 57120) where we previously removed 13 eCQMs from the eCQM measure set in order to develop a smaller, more specific subset of eCQMs.

In order to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, we believe it is appropriate to propose to remove additional eCQMs at this time to develop an even more streamlined set of the most meaningful eCQMs for hospitals. In selecting which eCQMs to propose for removal, we considered the relative benefits and costs associated with each eCQM in the measure set. Individual eCQMs are discussed in more detail below.

(a) AMI–8a

We are proposing to remove AMI–8a because the costs associated with implementing and maintaining this eCQM outweigh the associated benefit to beneficiaries because too few hospitals select to report on this measure. Only a single hospital reported on this measure for the CY 2016 reporting period. Because we do not receive enough data to conduct meaningful, statistically significant analysis, we believe the costs of maintaining this measure in the Program outweigh any associated benefit to patients, consumers, and providers—proposed removal Factor 8.

(b) CAC–3, STK–08, and STK–10

We are proposing to remove the CAC–3, STK–08, and STK–10 eCQMs, because we believe the costs associated with implementing and maintaining these eCQMs outweigh the benefit to beneficiaries because they do not provide information evaluating the clinical quality of the activity. Home Management Plan of Care Document Given to Patient/Caregiver (CAC–3) assesses the proportion of pediatric asthma patients discharged from an inpatient hospital stay with a Home Management Plan of Care (HMPC) document given to the pediatric asthma patient/caregiver. Stroke Education (STK–08) captures ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay and at discharge. Assessed for Rehabilitation (STK–10) captures ischemic or hemorrhagic stroke patients who were assessed for rehabilitation.

We have issued guidance that measure developers should avoid selecting or constructing measures that can be met primarily through documentation without evaluating the clinical quality of the activity—often satisfied with a checkbox, date, or code—for example, a completed assessment, care plan, or delivered instruction.[282] CAC–3, STK–08, and STK–10 are examples of those types of measures. In our effort to create a more parsimonious measure set, we assessed which measures are the least costly to report and most effective in particular priority areas, including stroke, and we believe these measures provide less benefit to providers and Beneficiaries, relative to their costs.

Furthermore, if our proposals to remove the STK–08 and STK–10 eCQMs are finalized as proposed, we believe the resulting set of four stroke eCQMs (STK–02, STK–03, STK–05, and STK–06) will be more meaningful to both patients and providers because they capture the proportion of ischemic stroke patients who are prescribed a statin medication,[283] specific anti-thrombolytic therapy,[284] and/or

[282] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf*.

[283] Measure specifications for STK–06 available at: *https://ecqi.healthit.gov/ecqm/measures/cms105v6*.

[284] Measure specifications for STK–02 and STK–05 available at: *https://ecqi.healthit.gov/ecqm/measures/cms104v6* and *https://ecqi.healthit.gov/ecqm/measures/cms072v6*.

anticoagulation therapy [285] at hospital discharges, which would address follow-up care and promote future preventative actions. Moreover, these remaining stroke eCQMs continue to be meaningful because ischemic strokes account for 87 percent of all strokes, and strokes are the fifth leading cause of death and disability.[286] We also note that the STK–08 and STK–10 eCQMs already have been removed from The Joint Commission's eCQM measure set.[287]

(c) ED–1

We are proposing to remove the Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) eCQM because we believe that among the ED measures in the eCQM measure set, Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–2) is more effective at driving quality improvement. We note that in section VIII.A.5.b.(8)(b) of the preamble of this proposed rule, above, we are proposing to remove the chart-abstracted versions of ED–1 and ED–2. As stated above, we believe that although ED–1 is an important metric for patients, ED–2 has greater clinical significance for quality improvement because it provides more actionable information—hospitals have greater ability to allocate resources and align inter-departmental communication to consistently reduce the time between decision to admit and time of inpatient admission. Hospitals have somewhat less ability to consistently reduce wait time between ED arrival and decision to admit, as measured by ED–1, due to the need to triage and prioritize more complex or urgent patients, which might inadvertently prolong ED wait times for less urgent patients. Also, the Hospital OQR Program includes an ED throughput measure, OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (81 FR 79755), which publicly reports similar data as captured by ED–1. Therefore, we believe the costs of implementing and maintaining the eCQM, as discussed above, outweigh the limited benefits of keeping the measure in the Program given that other measures in the Hospital IQR Program and in other CMS hospital quality programs are able to capture actionable data on ED wait times.

(d) EHDI–1a

We are proposing to remove the EHDI–1a eCQM because we believe the costs associated with implementing and maintaining the measure, as discussed above, outweigh the benefits to beneficiaries because newborn hearing screening is already widely practiced by hospitals as the standard of care and already mandated by many State laws. Forty-three States currently have statutes or rules related to newborn hearing screening and 28 of the 43 States require babies to be screened.[288] Thus, this measure may be duplicative with local regulations for most hospitals. Therefore, we believe the costs associated with the measure outweigh the associated benefits of keeping the measure in the Hospital IQR Program.

(e) PC–01

We are proposing to remove the eCQM version of PC–01. Due to the importance of child and maternal health, we are not proposing to also remove the chart-abstracted version of the measure because we believe all hospitals with a sufficient number of cases should be required to report data on this measure (adopted at 77 FR 53530). Although we have expressed in section XIII.A.4.b.ii.(8) of the preamble of this proposed rule our intent to move away from the use of chart-abstracted measures in quality reporting programs, our previously adopted policy requires that hospitals should need less time to submit data for this measure because, unlike the other chart-abstracted measures, hospitals are only required to submit several aggregate counts instead of potentially numerous patient-level charts. We note that submission of this measure places less information collection burden on hospitals than the other chart-abstracted measures because of the ease with which hospitals can simply submit their aggregate counts using our Web-Based Measure Tool through the QualityNet website (77 FR 53537). In addition, if the chart-abstracted version of this measure were removed from the Program, and hospitals could only elect to report the eCQM version of this measure as one of four required eCQMs, we believe that due to the low volume of patients relative to total adult hospital population, we would not receive enough data to produce meaningful analyses. Also, PC–01 is one of only two measures of child and maternal health in the Hospital IQR Program measure set (PC–05 eCQM being the other) and since eCQM data are not currently publicly reported, the chart-abstracted version of PC–01 is currently the only publicly reported measure of child and maternal health in the Program. However, retaining this measure in both eCQM and chart-abstracted form may be duplicative and costly. Consequently, we are proposing to remove the eCQM version of PC–01 while retaining the chart-abstracted version of PC–01.

Therefore, we believe the costs associated with implementing and maintaining the eCQM, as discussed above, outweigh the associated benefit to beneficiaries because the information is already collected and publicly reported in the chart-abstracted form of this measure for the Hospital IQR Program.

Thus, we are proposing to remove seven eCQMs as discussed above beginning with the CY 2020 reporting period/FY 2022 payment determination. If our proposals are finalized as proposed, the eCQMs remaining in the eCQM measure set would focus on: (a) ED wait times for admitted patients (ED–2), which addresses the Meaningful Measures Initiative quality priority of promoting effective communication and coordination of care; (b) Exclusive Breast Milk Feeding (PC–05), which addresses the Meaningful Measures Initiative quality priority that care is personalized and aligned with patients' goals; and (c) stroke care (STK–02, STK–03, STK–05, and STK–06) and VTE care (VTE–1 and VTE–2), which address the Meaningful Measures Initiative quality priority of promoting effective prevention and treatment.

In crafting our proposals to remove these seven eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years, we also considered proposing to remove these seven eCQMs one year earlier, beginning with the CY 2019 reporting period/FY 2021 payment determination. We establish program requirements considering all hospitals that participate in the Hospital IQR Program at a national level, which involves a wide spectrum of capabilities and resources with respect to eCQM reporting. In establishing our eCQM policies, we must balance the needs of hospitals with variable preferences and capabilities. Overall, across the range of capabilities and resources for eCQM reporting, stakeholders have expressed that they want more time to prepare for eCQM changes. Specifically, as noted in

[285] Measure specifications for STK–03 available at: *https://ecqi.healthit.gov/ecqm/measures/cms071v7*.

[286] *http://www.strokassociation.org/STROKEORG/AboutStroke/Impact-of-Stroke-Stroke-statistics_UCM_310728_Article.jsp#.WtDzy42Wzg9*.

[287] *https://www.jointcommission.org/the_joint_commission_measures_effective_january_1_2018/*.

[288] *http://www.infanthearing.org/ehdi-ebook/2017_ebook/1b%20Chapter1Evolution EHDI2017.pdf*.

the FY 2018 IPPS/LTCH PPS final rule, we have continued to receive frequent feedback (via email, webinar questions, help desk questions, and conference call discussions) from hospitals and health IT vendors about ongoing challenges of implementing eCQM reporting, including, ''a need for at least one year between new EHR requirements due to the varying 6- to 24-month cycles needed for vendors to code new measures, test and institute measure updates, train hospital staff, and rollout other upgraded features (82 FR 38355).''

We recognize that some hospitals and health IT vendors may prefer earlier removal in order to forgo maintenance on those eCQMs proposed for removal. In preparation for this proposed rule, we weighed the relative burdens and costs associated with removing these measures beginning with the CY 2019 reporting period/FY 2021 payment determination or beginning with the CY 2020 reporting period/FY 2021 payment determination. Ultimately, in order to be responsive to the previous stakeholder feedback we have received, we are proposing to remove these seven eCQMs beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years, even if as a result some hospitals may have to perform measure maintenance on measures that would be removed the following year. We believe our proposal to remove these eCQMs would spare hospitals that have already allocated and expended resources in 2018 in preparation for the CY 2019 reporting period that begins January 1, 2019 from the burden of unnecessarily expended resources or expending additional time and resources to update their EHR systems or adjust the eCQMs they selected to report for the CY 2019 reporting period/FY 2021 payment determination.

In this proposed rule, we are striving to establish program requirements that reflect the wide range of capabilities and resources of hospitals for eCQM reporting. Our proposal would allow more advanced notice of eCQMs that would and would not be available to report for the CY 2020 reporting period/FY 2022 payment determination. Therefore, we are proposing to remove the AMI–8a, CAC–3, ED–1, EHDI–1a, PC–01, STK–08, and STK–10 eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We refer readers to section VIII.A.5.b.(9) of the preamble of this proposed rule for our proposals to remove these seven eCQMs from the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). We also refer readers to sections VIII.A.11.d. of the preamble of this proposed rule for our proposals on the eCQM reporting requirements for the CY 2019 reporting period/FY 2021 payment determination, including further discussion on the 2015 Edition of CEHRT.

We are inviting public comment on our proposal as discussed above, including the specific measures proposed for removal and the timing of removal from the Program.

c. Summary of Hospital IQR Program Measures Proposed for Removal

In this proposed rule, we are proposing to remove a total of 39 measures from the program, as summarized in the table below:

SUMMARY OF HOSPITAL IQR PROGRAM MEASURES PROPOSED FOR REMOVAL

Short name	Measure name	First payment determination year proposed for removal	NQF #
Structural Patient Safety Measures			
Safe Surgery Checklist	Safe Surgery Checklist Use	FY 2020	N/A
Patient Safety Culture	Hospital Survey on Patient Safety Culture	FY 2020	N/A
Patient Safety Measures			
PSI 90	Patient Safety and Adverse Events Composite	FY 2020	0531
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	FY 2021	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2021	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	FY 2021	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.	FY 2021	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2021	1716
Claims-Based Coordination of Care Measures			
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	FY 2020	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	FY 2020	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	FY 2020	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Heart Failure (HF) Hospitalization.	FY 2020	0330
READM–30–PNA	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization.	FY 2020	0506

SUMMARY OF HOSPITAL IQR PROGRAM MEASURES PROPOSED FOR REMOVAL—Continued

Short name	Measure name	First payment determination year proposed for removal	NQF #
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	FY 2020	1551
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization.	FY 2020	N/A
Claims-Based Mortality Measures			
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	FY 2020	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	FY 2020	0229
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	FY 2021	1893
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	FY 2021	0468
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	FY 2022	2558
Claims-Based Patient Safety Measure			
Hip/Knee Complications	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	FY 2023	1550
Claims-Based Payment Measures			
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital Measure	FY 2020	2158
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	FY 2020	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure.	FY 2020	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure.	FY 2020	N/A
AA Payment	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure.	FY 2020	N/A
Chole and CDE Payment	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure.	FY 2020	N/A
SFusion Payment	Spinal Fusion Clinical Episode-Based Payment Measure	FY 2020	N/A
Chart-Abstracted Clinical Process of Care Measures			
IMM–2	Influenza Immunization	FY 2021	1659
VTE–6	Incidence of Potentially Preventable VTE [Venous Thromboembolism]	FY 2021	+
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients.	FY 2021	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	FY 2022	0497
EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))			
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	FY 2022	+
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver.	FY 2022	+
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients.	FY 2022	0495
EHDI–1a	Hearing Screening Prior to Hospital Discharge	FY 2022	1354
PC–01	Elective Delivery	FY 2022	0469
STK–08	Stroke Education	FY 2022	+
STK–10	Assessed for Rehabilitation	FY 2022	0441

* Measure is proposed for removal in chart-abstracted form, but will be retained in eCQM form.
+ NQF endorsement removed.

6. Summary of Previously Adopted Hospital IQR Program Measures for the FY 2020 Payment Determination

The table below summarizes the Hospital IQR Program measure set for the FY 2020 payment determination (including previously adopted measures, but not including measures proposed for removal beginning with the FY 2020 payment determination in this proposed rule):

[289] We note that measure stewardship of the recalibrated version of the Death Rate among

Continued

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PAYMENT DETERMINATION *

Short name	Measure name	NQF #
	Healthcare-Associated Infection Measures	
CAUTI	National Healthcare Safety Network Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
	Claims-Based Patient Safety Measures	
Hip/Knee Complications	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications [289]	0351
	Claims-Based Mortality Measures	
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–PN	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
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	
ED–1 **	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 **	Admit Decision Time to ED Departure Time for Admitted Patients	0497
IMM–2	Influenza Immunization	1659
PC–01 **	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
VTE–6	Incidence of Potentially Preventable Venous Thromboembolism	+
	EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))	
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	+
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1 **	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 **	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354

Surgical Inpatients with Serious Treatable Complications measure is transitioning from AHRQ to CMS and, as part of the transition, the measure will be referred to as the CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) when it is used in CMS quality programs.

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2020 PAYMENT DETERMINATION *—Continued

Short name	Measure name	NQF #
PC–01 **	Elective Delivery	0469
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
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
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)

* As discussed in section VIII.A.5. of the preamble of this proposed rule, we are proposing to remove 19 measures—17 claims-based measures and two structural measures—beginning with the FY 2020 payment determination. These measures, which had previously been finalized for the FY 2020 payment determination are not included in this summary table.
** Measure listed twice, as both chart-abstracted and eCQM versions.
+ NQF endorsement has been removed.

7. Summary of Previously Adopted Hospital IQR Program Measures for the FY 2021 Payment Determination

The table below summarizes the Hospital IQR Program measure set for the FY 2021 payment determination (including previously adopted measures, but not including measures proposed for removal beginning with the FY 2021 payment determination in this proposed rule):

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2021 PAYMENT DETERMINATION

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
Hip/Knee Complications	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	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		
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC–01 *	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2021 PAYMENT DETERMINATION—Continued

Short name	Measure name	NQF #
EHR-Based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
AMI–8a	Primary Percutaneous Coronary Intervention Received within 90 minutes of Hospital Arrival.	+
CAC–3	Home Management and Plan of Care Document Given to Patient/Caregiver	+
ED–1	Median Time From ED Arrival to ED Departure for Admitted ED Patients (ED–1)	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients (ED–2)	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01 *	Elective Delivery	0469
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	0438
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit 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)

* Measure listed twice, as both chart-abstracted and eCQM versions.
+ NQF endorsement has been removed.

8. Summary of Previously Adopted Hospital IQR Program Measures for the FY 2022 Payment Determination and Subsequent Years

The table below summarizes the Hospital IQR Program measure set for the FY 2022 payment determination (including previously adopted measures, but not including measures proposed for removal beginning with the FY 2022 payment determination in this proposed rule) and subsequent years:

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
Healthcare-Associated Infection Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
Hip/Knee Complications *	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
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

PREVIOUSLY ADOPTED MEASURES FOR THE FY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
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)

* Proposed for removal from the Hospital IQR Program beginning with the FY 2023 payment determination, as discussed in section VIII.A.5.b.(5) of the preamble of this proposed rule.

9. Possible New Quality Measures, Measure Topics, and Other Future Considerations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512), we outlined considerations to guide us in selecting new quality measures to adopt into the Hospital IQR Program. We also refer readers to section I.A.2. of the preamble of this proposed rule where we describe the Meaningful Measures Initiative—quality priorities that we have identified as high impact measurement areas that are relevant and meaningful to both patients and providers.

In keeping with these considerations, we are inviting public comment on the potential future inclusion of a hospital-wide mortality measure in the Hospital IQR Program, specifically whether to propose to adopt a Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure or a Hybrid Hospital-Wide, All-Cause, Risk-Standardized Mortality measure. We are also considering a newly specified eCQM for possible concurrent inclusion in future years of the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), the Opioid Harm Electronic Clinical Quality Measure (eCQM). We also seek public input on the future development and adoption of eCQMs more generally (for example, burdens, incentives). These topics are discussed in more detail below.

a. Potential Inclusion of Claims-Only Hospital-Wide Mortality Measure and/or Hybrid Hospital-Wide Mortality Measure With Electronic Health Record Data

(1) Background

Mortality is an important health outcome that is meaningful to patients and providers, and the vast majority of patients admitted to the hospital have survival as a primary goal. However, estimates using data from 2002 to 2008 suggest that more than 400,000 patients die each year from preventable harm in hospitals.[290] While we do not expect mortality rates to be zero, studies have shown that mortality within 30 days of hospital admission is related to quality of care, and that high and variable mortality rates across hospitals indicate opportunities for improvement.[291] [292] In addition to the harm to individuals, their families, and caregivers resulting from preventable death, there are also significant financial costs to the healthcare system associated with high and variable mortality rates. While capturing monetary savings for preventable mortality events is challenging, using two recent estimates of the number of deaths due to preventable medical errors and assuming an average of ten lost years of life per death (valued at $75,000 per year in lost quality adjusted life years), the annual direct and indirect cost of potentially preventable deaths could be as much as $73.5 to $735 billion.[293] [294] [295]

Existing condition-specific mortality measures adopted into the Hospital IQR Program support quality improvement work targeted toward patients with a set of common medical conditions, such as heart failure, acute myocardial infarction, or pneumonia. The use of these measures may have contributed to national declines in hospital mortality rates for the measured conditions and/or procedures.[296] However, a measure of hospital-wide mortality captures a hospital's performance across a broader set of patients and across more areas of the hospital. Because more patients are included in the measure, a hospital-

[290] James JT. A new, evidence-based estimate of patient harms associated with hospital care. *Journal of patient safety.* 2013;9(3):122–128.

[291] Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. *JAMA.* 2006;295(16):1912–1920.

[292] Writing Group for the Checklist- I.C.U. Investigators, Brazilian Research in Intensive Care Network. Effect of a quality improvement intervention with daily round checklists, goal setting, and clinician prompting on mortality of critically ill patients: A randomized clinical trial. *JAMA.* 2016;315(14):1480–1490.

[293] Institute of Medicine. To Err is Human: Building a Safer Health System. 1999; Available at: *https://iom.nationalacademies.org/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf.*

[294] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs. 2011;30(4):581–589.

[295] Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. *Journal of health care finance.* 2012;39(1):39–50.

[296] Suter LG, Li SX, Grady JN, et al. National patterns of risk-standardized mortality and readmission after hospitalization for acute myocardial infarction, heart failure, and pneumonia: update on publicly reported outcomes measures based on the 2013 release. *Journal of general internal medicine.* 2014;29(10):1333–1340.

wide mortality measure also captures the performance for smaller volume hospitals that would otherwise not have sufficient cases to calculate condition- or procedure-specific mortality measures.

We developed two versions of a hospital-wide, all-cause, risk-standardized mortality measure: one that is calculated using only claims data (the Claims-Only Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the ''Claims-Only HWM measure'')); and a hybrid version that uses claims data to define the measure cohort and a combination of data from electronic health records (EHRs) and claims for risk adjustment (Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the ''Hybrid HWM measure'')). The goal of developing hospital-wide mortality measures is to assess hospital performance on patient outcomes among patients for whom mortality is likely to present an important quality signal and those where the hospital can positively influence the outcome for the patient. Both versions of the measure address the Meaningful Measures Initiative quality priority of promoting effective treatment to reduce risk-adjusted mortality.

Several stakeholder groups were engaged throughout the development process, including a Technical Work Group and a Patient and Family Work Group, as well as a national, multi-stakeholder Technical Expert Panel consisting of a diverse set of stakeholders, including providers and patients. These groups were convened by the measure developer under contract with us and provided feedback on the measure concept, outcome, cohort, risk model variables, and reporting results. The measure developer also solicited stakeholder feedback during measure development as required in the Measures Management System (MMS) Blueprint.[297]

We developed a Hybrid HWM measure in addition to a Claims-Only HWM measure in order to move toward greater use of EHR data for quality measurement, and in response to stakeholder feedback that is important to include clinical data in outcome measures (80 FR 49702 through 49703). The Hybrid HWM measure is harmonized with the Claims-Only HWM measure. Both measures use the same cohort definition, outcome assessment, and claims-based risk variables (discussed in more detail below). The Hybrid HWM measure builds upon prior efforts to use of a set of core clinical data elements extracted from hospital EHRs for each hospitalized Medicare FFS beneficiary over the age of 65 years, as outlined in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698). The core clinical data elements are data which are routinely collected on hospitalized adults, extraction from hospital EHRs is feasible, and the data can be utilized as part of specific quality outcome measures. The Hybrid HWM measure's core clinical data elements are very similar to, but not precisely that same as, those used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data measure (NQF #2879), for which we are currently collecting data from hospitals on a voluntary basis and are considering proposing as a required measure as early as the FY 2023 payment determination (82 FR 38350 through 38355). For more detail about the core clinical data elements used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data measure (NQF #2879), we refer readers to our discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698 through 49704) and the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors report (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

The Claims-Only Hospital-Wide All-Cause Risk Standardized Mortality Measure (MUC17–195) and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (MUC17–196) were included in a publicly available document entitled ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and have been reviewed by the NQF MAP Hospital Workgroup. The MAP conditionally supported both measures pending NQF review and endorsement, as referenced in the 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS (available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*). The MAP also recommended the Hybrid HWM measure have a voluntary reporting period before mandatory implementation.[298]

The MAP noted both measures are important measures for patient safety, and that these measures could help reduce deaths due to medical errors.[299] We agree with MAP stakeholder concerns regarding the need for the NQF endorsement process to ensure the measures have appropriate clinical and social risk factors in the risk adjustment models and address necessary exclusions to ensure the measure does not disproportionately penalize facilities that may treat more complex patients.[300] The MAP also expressed concern regarding the potential unintended consequences of unnecessary interventions for patients at the end of life; [301] however, this issue was carefully addressed during measure development by excluding patients at the end of life and for whom survival is unlikely to be the goal of care from the measure cohort based upon the TEP and patient work group input. Specifically, the measure does not include patients enrolled in hospice in the 12 months prior to admission, on admission, or within 2 days of admission; the measure also does not include patients admitted primarily for cancer that are enrolled in hospice at any time during the admission, those admitted primarily for metastatic cancer, and those admitted for specific diagnoses with limited chances of survival.

The MAP further suggested that condition-specific mortality measures may be more actionable for providers and informative for consumers.[302] While service-line divisions may not be as granular as condition-specific measures, we believe a single comprehensive marker of hospital quality encourages organization-wide improvement, allows more hospitals to meet volume requirements for inclusion, offers more rapid detection of changes in performance due to performance being based on the most recent year of data available, and aligns with to the Meaningful Measures Initiative by creating the framework for stakeholders to have fewer measures to track and a single score to reference. We plan to submit both measures to NQF for endorsement proceedings as part of the Patient Safety Committee as early as

[297] CMS Measures Management System Blueprint (Blueprint v 13.0). CMS. 2017. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf*.

[298] Measure Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[299] Ibid.

[300] Ibid.

[301] Ibid.

[302] Ibid.

FY 2019, after the measures have been fully specified for use with ICD–10 data.

(2) Overview of Measures

Both the Claims-Only HWM measure and the Hybrid HWM measure capture hospital-level, risk-standardized mortality within 30 days of hospital admission for most conditions or procedures. The measures are reported as a single summary score, derived from the results of risk-adjustment models for 13 mutually exclusive service-line divisions (categories of admissions grouped based on discharge diagnoses or procedures), with a separate risk model for each of the 13 service-line divisions. The 13 service-line divisions include: 8 non-surgical divisions and 5 surgical divisions. The non-surgical divisions are: Cancer; cardiac; gastrointestinal; infectious disease; neurology; orthopedics; pulmonary; and renal. The surgical divisions are: Cancer; cardiothoracic; general; neurosurgery; and orthopedics. Hospitalizations are eligible for inclusion in the measure if the patient was hospitalized at a non-Federal, short-stay acute care hospital. To compare mortality performance across hospitals, the measure accounts for differences in patient characteristics (patient case mix) as well as differences in the medical services provided and procedures performed by hospitals (hospital service mix). In addition, the Hybrid HWM Measure employs a combination of administrative claims data and clinical EHR data to enhance clinical case mix adjustment with additional clinical data.

Our goal is to more comprehensively measure the mortality rates of hospitals, including to improve the ability to measure mortality rates in smaller volume hospitals. The cohort definition attempts to capture as many admissions as possible for which survival would be a reasonable indicator of quality and for which adequate risk adjustment is possible. We assume survival would be a reasonable indicator of quality for admissions fulfilling two criteria: (1) Survival is most likely the primary goal of the patient when they enter the hospital; and (2) the hospital can reasonably influence the patient's chance of survival through quality of care. These measures would provide information to hospitals that can facilitate quality improvement efforts for hospital settings, types of care, and types of patients not included in currently available condition-and procedure-specific mortality measures. Also, these measures would provide more transparency about the quality of care in clinical areas not captured in the current condition- and procedure-specific measures.

Additional information on the development of both the Claims-Only and Hybrid versions of the HWM measure can be found on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(3) Data Sources

Both the Claims-Only and Hybrid versions of the HWM measure use Part A Medicare administrative claims data from Medicare FFS beneficiaries aged between 65 and 94 years, and use one year of data. Part A data from the 12 months prior to the index admission are used for risk adjustment.

The Hybrid HWM measure uses two sources of data for the calculation of the measure: Medicare Part A claims and a set of core clinical data elements from hospitals' EHRs. Claims and enrollment data are used to identify index admissions included in the measure cohort, in the risk-adjustment model, and to assess the 30-day mortality outcome. These data are merged with the core clinical data elements for eligible patient admissions from each hospital's EHR. The data elements are the values for a set of vital signs and common laboratory tests collected at presentation and used for risk-adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are aged between 65 and 94 years), in addition to data from claims.

(4) Outcome

The outcome of interest for both the Claims-Only and Hybrid versions of the HWM measure is the same, all-cause 30-day mortality. We define all-cause mortality as death from any cause within 30 days of the index hospital admission date.

(5) Cohort

The cohorts for both the Claims-Only HWM and Hybrid versions of the HWM measure are the same. The measure cohorts consist of Medicare FFS beneficiaries, aged between 65 and 94 years, discharged from non-federal acute care hospitals.

The Claims-Only HWM measure and Hybrid HWM measure were developed using ICD–9 codes. The measures are currently being updated for use with ICD–10 codes; ICD–10 updates will be completed prior to NQF submission and potential future implementation. Similar to the existing Hospital-Wide All-Cause Unplanned Readmission measure (NQF #1789), which was adopted into the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule beginning with the FY 2015 payment determination (77 FR 53521 through 53528), the Claims-Only HWM measure and Hybrid HWM measure include a large and diverse number of admissions represented by thousands of included ICD–9 codes. We used the AHRQ Clinical Classification Software (CCS) [303] to group numerous diagnostic and procedural ICD–9 codes into the clinically meaningful categories defined by the AHRQ grouper. Both the Claims-Only and Hybrid versions of the HWM measure use those CCS categories as part of cohort specification and risk-adjustment, including the 13 service-line risk models.

For the AHRQ CCSs and individual ICD–9–CM codes that define the measure development cohort, we refer readers to the measure methodology reports on our website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(6) Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for both the Claims-Only and Hybrid versions of the HWM measure are the same. For both versions of the HWM measure, the cohort currently includes Medicare FFS patients who: (1) Were enrolled in Medicare FFS Part A for the 12 months prior to the date of admission and during the index admission; (2) have not been transferred from another inpatient facility; (3) were admitted for acute care (do not have a principal discharge diagnosis of a psychiatric disease or do not have a principal discharge diagnosis of ''rehabilitation care; fitting of prostheses and adjustment devices''); (4) are aged between 65 and 94 years; (5) are not enrolled in hospice at the time of or in the 12 months prior to their index admission; (6) are not enrolled in hospice within two days of admission; (7) are without a principal diagnosis of cancer and enrolled in hospice during their index admission; (8) are without any diagnosis of metastatic cancer; and (9) are without a principal discharge diagnosis of a condition which hospitals have limited ability to influence survival, including: Anoxic brain damage; persistent vegetative state; prion diseases such as Creutzfeldt-Jakob disease, Cheyne-Stokes respiration; brain death; respiratory arrest; or

[303] Clinical Classifications Software (CCS) for ICD–9–CM Fact Sheet. Accessed at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp*.

cardiac arrest without a secondary diagnosis of acute myocardial infarction.

Both the Claims-Only and Hybrid versions of the HWM measure currently exclude the following index admissions for patients: (1) With inconsistent or unknown vital status; (2) discharged against medical advice; (3) with an admission for crush injury, burn, intracranial injury, or spinal cord injury; (4) with specific principal discharge diagnosis codes for which mortality may not be a quality signal; (5) with an admission in a CCS condition or procedure categorized as in the service-line divisions: Other Surgical Procedures or Other Non-Surgical Conditions (this exclusion is being reassessed to include these patients in the final measure); and (6) with an admission in a low-volume CCS (within a particular service-line division), defined as equal to or less than 100 patients with that principle diagnosis across all hospitals.

For both the Claims-Only and Hybrid versions of the HWM measure, each index admission is assigned to one of 13 mutually exclusive service-line divisions. For details on how each admission is assigned to a specific service-line division, and for a complete description and rationale of the inclusion and exclusion criteria, we refer readers to the methodology reports found on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(7) Risk-Adjustment

Both the Claims-Only and Hybrid versions of the HWM measure adjust for both case mix differences (clinical status of the patient, accounted for by adjusting for age and comorbidities) and service-mix differences (the types of conditions and procedures cared for and procedures conducted by the hospital, accounted for by the discharge condition category), and use the same patient comorbidities in the risk models. Patient comorbidities are based on inpatient hospital administrative claims during the 12 months prior to and including the index admission derived from ICD–9 codes grouped into the CMS condition categories (CMS–CCs). The measures are currently being updated for use with ICD–10 codes; ICD–10 updates will be completed prior to NQF submission and potential future adoption.

The Hybrid HWM measure also includes the core clinical data elements from patients' EHRs in the case mix adjustment. The core clinical data elements are derived from information captured in the EHR during the index admission only, and are listed below.

CURRENTLY SPECIFIED CORE CLINICAL DATA ELEMENT VARIABLES

Data elements	Units of measurement	Time window for first captured values
Heart Rate	Beats per minute	0–2 hours.
Systolic Blood Pressure	mmHg	0–2 hours.
Temperature	Degrees (Fahrenheit or Celsius)	0–2 hours.
Oxygen Saturation	Percent	0–2 hours.
Hemoglobin	g/dL	0–24 hours.
Platelet	Count	0–24 hours.
White Blood Cell Count	Cells/mL	0–24 hours.
Sodium	mEq/L	0–24 hours.
Bicarbonate	mmol/L	0–24 hours.
Creatinine	mg/dL	0–24 hours.

The core clinical data elements are clinical information meant to reflect a patient's clinical status upon arrival to the hospital. For more details on how the risk variables in each measure were chosen, we refer readers to the methodology reports found on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*.

(8) Calculating the Risk-Standardized Mortality Rate (RSMR)

The method for calculating the RSMR for both the Claims-Only and the Hybrid versions of the HWM measure is the same. Index admissions are assigned to one of 13 mutually exclusive service-line divisions consisting of related conditions or procedures. For each service-line division, the standardized mortality ratio (SMR) is calculated as the ratio of the number of ''predicted'' deaths to the number of ''expected'' deaths at a given hospital. For each hospital, the numerator of the ratio is the number of deaths within 30 days predicted based on the hospital's performance with its observed case mix and service mix, and the denominator is the number of deaths expected based on the nation's performance with that hospital's case mix and service mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses.

The service-line SMRs are then pooled for each hospital using an inverse variance-weighted mean to create a hospital-wide composite SMR. The inverse variance-weighted mean can be interpreted as a weighted average of all SMRs that takes into account the precision of SMRs. The composite SMR is multiplied by the national observed mortality rate to produce the RSMR. For additional details regarding the measure specifications to calculate the RSMR, we refer readers to the Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure: Measure Methodology for Public Comment report and Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors: Measure Methodology for Public Comment report, which are posted on the CMS website at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We are inviting public comment on the possible future inclusion of one or both hospital-wide mortality measures in the Hospital IQR Program simultaneously. We are also considering possible future inclusion of the Hybrid HWM measure in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for Clinical Quality Measures (CQM) electronic reporting by eligible hospitals and CAHs. We are also inviting public comment on other aspects of the measure. Specifically, we are seeking public comment on the following: (1) Feedback about the

service-line division structure of the measure; (2) input on the measure testing approach, particularly if there is any additional validity testing that would be meaningful; and (3) how the measure results might be presented to the public, including ways that we could present supplemental hospital performance information in public reporting, such as service-line division-level results, to create a more meaningful and usable measure and ways that we could report more information about hospitals in a No Different From National Average group (defined using 95 percent confidence intervals) to help clinicians and patients use the measure results to improve patient care and make informed choices.

b. Potential Future Inclusion of the Hospital Harm—Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM)

(1) Background

Opioids are among the most frequently implicated medications in adverse drug events among hospitalized patients. The most serious opioid-related adverse events include those with respiratory depression, which can lead to brain damage and death. Opioid-related adverse events have both negative patient impacts and financial implications. These patients have been noted to have 55 percent longer lengths of stay, 47 percent higher costs, 36 percent higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events.[304] While noting that data are limited, The Joint Commission suggested that opioid-induced respiratory arrest may contribute substantially to the 350,000–750,000 in-hospital cardiac arrests annually.[305]

Most opioid-related adverse events are preventable. Of the opioid-related adverse drug events reported to The Joint Commission's Sentinel Event database,[306] 47 percent were due to a wrong medication dose, 29 percent to improper monitoring, and 11 percent to other causes (for example, medication interactions and/or drug reactions). In addition, in an analysis of a malpractice claims database, a review of cases in which there was opioid-induced respiratory depression among post-operative surgical patients, 97 percent of these adverse events were judged preventable with better monitoring and response.[307] While hospital quality interventions such as, proper dosing, adequate monitoring, and attention to potential drug interactions that can lead to overdose are key to prevention of opioid-related respiratory events, the use of these practices can vary substantially across hospitals.

Administration of opioids also varies widely by hospital, ranging from 5 percent in the lowest-use hospital to 72 percent in the highest-use hospital.[308] Notably, hospitals that use opioids most frequently have increased adjusted risk of severe opioid-related adverse events.[309] Surgical patients are at particular risk of these adverse events because opioid administration is common in this population. For example, among a diverse group of surgical patients undergoing common surgical procedures at a large medical center, 98.6 percent received opioids and 13.6 percent of those patients experienced an opioid-related adverse drug event.[310] Reduction of adverse events in surgical and non-surgical patients receiving opioids, may be enhanced by measuring the rates of these events at each hospital in a systematic, comparable way. We have developed the Hospital Harm—Opioid-Related Adverse Events eCQM to assess the rates of these adverse events as well as the variation in rates among hospitals.

(2) Overview of Measure

The Hospital Harm—Opioid-Related Adverse Events eCQM outcome measure assesses, by hospital, the proportion of patients who had an opioid-related adverse event. This measure addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care. The measure uses the administration of naloxone, an opioid reversal agent that has been used in a number of studies as an indicator of opioid-related adverse respiratory events, to indicate a harm to a patient.[311] [312] The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. This measure focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into the emergency department. We acknowledge that some stakeholders have expressed concern that some providers could withhold the use of naloxone, believing that may help those providers avoid poor performance on this quality measure. This measure is not intended to incentivize hospitals to not administer naloxone to patients who are in respiratory depression, but rather incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent respiratory depression. In addition, the aim of this measure is not to identify preventability of an individual harm instance or whether each instance of harm was an error, but rather to assess the overall rate of the harm within a hospital incorporating a definition of harm that is likely to be reduced as a result of hospital best practice.

As with all quality measures we develop, testing was performed to establish the feasibility of the measure, data elements, and validity of the numerator. Clinical adjudicators reviewed medical records on each instance of a harm identified through query of the EHR data to confirm naloxone was in fact administered to reverse symptoms of opioid overdose. Additional testing is currently being performed to establish the data element validity using output from the Measure Authoring Tool (MAT) [313] in multiple hospitals, using multiple EHR systems. The MAT is a web-based tool used to develop the electronic measure

[304] Kessler ER, Shah M, Gruschkkus SK, et al. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy.* 2013; 33(4):383–391.

[305] Overdyk FJ. Postoperative respiratory depression and opioids. Initiatives in Safe Patient Care. 2009; Available at: *http://files.sld.cu/anestesiologia/files/2012/01/postoperative-respiratory-depression-opioids.pdf.*

[306] The Joint Commission. Safe use of opioids in hospitals. *The Joint Commission Sentinel Event Alert.* 2012; 49:1–5. *https://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf.*

[307] Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. *Anesthesiology.* 2015; 122(3):659–665.

[308] Herzig SJ, Rothberg MB, Cheung M, et al. Opioid utilization and opioid-related adverse events in nonsurgical patients in US hospitals. *J Hosp Med.* 2014; 9(2):73–81.

[309] Ibid.

[310] Kessler ER, Shah M, Gruschkkus SK, et al. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy.* 2013; 33(4):383–391.

[311] Eckstrand JA, Habib AS, Williamson A, et al. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009; 3:18.

[312] Nwulu U, Nirantharakumar K, Odesanya R, et al. Improvement in the detections of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. *Eur J Clin Pharmacol.* 2013; 69(2):255–259.

[313] The Measure Authoring Tool (MAT) is a web-based tool used by measure developers in the creation of eMeasures. For additional information, we refer readers to: *https://www.emeasuretool.cms.gov/.*

specifications, which expresses complicated measure logic in several formats including a human-readable document. The electronically extracted data would be validated by comparison to medical chart abstracted data.

This measure addresses the Meaningful Measures Initiative quality priority of making care safer by reducing harm caused in the delivery of care discussed in section I.A.2. of the preamble of this proposed rule. The Hospital Harm—Opioid-related Adverse Events (MUC17–210) was included in a publicly available document entitled ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*). This measure was reviewed by the NQF MAP Hospital Workgroup in December 2017 and received the recommendation to refine and resubmit for consideration for programmatic inclusion, as referenced in the 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS (available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*). For additional information and discussion of concerns and considerations raised by the MAP related to this measure, we refer readers to the December 2017 NQF MAP Hospital Workgroup meeting transcript (available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87148*).

MAP stakeholders acknowledged the significant health risks associated with opioid-related adverse events, but recommended adjusting the numerator to consider the impact on chronic opioid users.[314] Accordingly, we will address this issue in upcoming testing and NQF review. Regarding MAP stakeholder concern that the measure needs to be tested in more facilities to demonstrate reliability and validity, as stated previously, we are currently testing the MAT output for this measure in multiple hospitals that use a variety of EHR systems.[315] We plan to submit this measure for NQF endorsement as part of the Patient Safety Committee in November 2018.

(3) Cohort

The measure denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the 1-year measurement period. The measure includes inpatient admissions that were initially seen in the emergency department or in observational status and then admitted to the hospital.

(4) Outcome

The numerator for this electronic outcome measure is the number of patients who received naloxone outside of the operating room either: (1) After 24 hours from hospital arrival; or (2) during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to the naloxone administration. We narrowed cases to exclude naloxone use in the operating room where it could be part of the sedation plan as administered by an anesthesiologist. Use of naloxone for procedures outside of the operating room (such as bone marrow biopsy) are counted in the numerator as it would indicate the patient was over sedated. These criteria exist to ensure patients are not considered to have experienced harm if they receive naloxone in the first 24 hours due to an opioid overdose that occurred in the community prior to hospital arrival. We do not require the administration of an opioid prior to naloxone after 24 hours from hospital arrival because an event occurring 24 hours after admission is most likely due to hospitals' administration of opioids. By limiting the requirement of documented opioid administration to the first 24 hours of the encounter, we are reducing the complexity of the measure logic and therefore the burden of implementation for hospitals. For more information about the measure specifications, we refer readers to our MAT Header (measure specs) and framing document (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Public-Comments.html*).

We are inviting public comment on the possible future inclusion of the Hospital Harm—Opioid-related Adverse Events eCQM in the Hospital IQR Program. Specifically, we are seeking public comment on whether to: (1) Initially introduce this measure as voluntary; (2) adopt the measure into the existing eCQM measure set from which hospitals currently select four to report; or (3) adopt the measure as mandatory for all hospitals to report. In addition, we are seeking public comment on ways to address any potential unintended consequences resulting from future implementation of this measure. We are also considering future adoption of this measure in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for Clinical Quality Measures (CQM) electronic reporting by eligible hospitals and CAHs.

c. Potential Future Development and Adoption of eCQMs Generally

Stakeholders continue to identify areas for improvement in the implementation of eCQMs under a variety of CMS programs, including the Hospital IQR Program and the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). While effective utilization of eCQMs promises greater efficiency and more timely access to data to support quality improvement activities, various types of costs associated with these measurement approaches detract from these benefits. Moreover, some providers may have low awareness of the resources and tools available to help address issues that arise in utilizing eCQMs.

Program design and operations associated with measurement aspects of these programs can be a significant source of cost for providers. Uncertainty around rapidly shifting timelines and requirements can pose significant financial and operational planning challenges for organizations, while lack of alignment across programs results in further complexity. In addition, the implementation of eCQMs within the EHR is a significant source of cost. Health IT products vary widely in the eCQMs they offer, and incorporating new measure specifications into a product, along with validation and testing of the updates, can be challenging and time-consuming. Lack of transparency from developers around data sources within the EHR, mapping, measure calculations, and reporting schemas, can hinder providers' ability to implement eCQMs and ensure the accuracy of results. Moreover, challenges in extracting data from the EHR and integrating with other applications can serve as a source of cost for providers seeking to bring together different technology solutions and work with other third party services to complete reporting and quality improvement activities.

Stakeholders have expressed support for increasing the availability of new eCQMs, developing eCQMs that focus on patient outcomes and higher impact measurement areas, and exploring how eCQMs can reduce the costs and information collection burden associated with chart-abstracted

[314] Measure Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[315] Ibid.

measures. However, they have also identified barriers which may contribute to a lack of adequate development of eCQMs and limit their potential, including long development timelines, lack of guidelines/prioritization of and participation in eCQM development, limited field testing, and program policies that limit innovation by focusing on ''least common denominator'' approaches.

We are seeking stakeholder feedback on ways that we could address these and other challenges related to eCQM use. Specifically, we are inviting comment on the following questions: (1) What aspects of the use of eCQMs are most costly to hospitals and health IT vendors?; (2) What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM costs?; (3) What are the most significant barriers to the availability and use of new eCQMs today?; (4) What specifically would stakeholders like to see us do to reduce costs and maximize the benefits of eCQMs?; (5) How could we encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?; (6) How could we encourage hospitals and health IT vendors to engage in testing new eCQMs?; (7) Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?; (8) What ways could we incentivize or reward innovative uses of health IT that could reduce costs for hospitals?; and (9) What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

10. Accounting for Social Risk Factors in the Hospital IQR Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324 through 38326), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[316] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[317] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress, which was required by the IMPACT Act of 2014, found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act of 2014, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[318] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[319] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: To explore other factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned us to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

Specifically, in the FY 2018 IPPS/LTCH PPS proposed and final rules for the Hospital Inpatient Quality Reporting (IQR) Program, we invited and received public comment on: (1) Which social risk factors provide the most valuable information to stakeholders; (2) providing hospitals with confidential feedback reports containing stratified results for certain Hospital IQR Program measures, specifically the Pneumonia Readmission measure (NQF #0506) and

[316] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[317] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[318] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[319] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

the Pneumonia Mortality measure (NQF #0468); (3) a potential methodology for illuminating differences in outcomes rates among patient groups within a hospital that would also allow for a comparison of those differences, or disparities, across hospitals; (4) an alternative methodology that compares performance for patient subgroups across hospitals but does not provide information on within hospital disparities and any additional suggested methodologies for calculating stratified results by patient dual eligibility status; and (5) future public reporting of these same measures stratified by patient dual eligibility status on the *Hospital Compare* website (82 FR 38407). For the Hospital IQR Program in general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care (82 FR 38404). Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment (82 FR 38404).

As a next step, we are considering options to reduce health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We are considering implementing the two above-mentioned methods to promote health equity and improve healthcare quality for patients with social risk factors. The first method (the hospital-specific disparity method) would promote quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method would also allow for a comparison of those differences, or disparities, across hospitals, so hospitals could assess how well they are closing disparities gaps compared to other hospitals. The second methodological approach is complementary and would assess hospitals' outcome rates for subgroups of patients, such as dual eligible patients, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors.

We acknowledge the complexity of interpreting stratified outcome measures. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404 through 38409), due to this complexity, and prior to any future public reporting of stratified measure data, we plan to stratify the Pneumonia Readmission measure (NQF #0506) data by highlighting both hospital-specific disparities and readmission rates specific for dual-eligible beneficiaries across hospitals for dual-eligible patients in hospitals' confidential feedback reports beginning Fall 2018. In FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38409), we explained that we believe the Pneumonia Readmission measure and the Pneumonia Mortality measure are appropriate first measures to stratify, because we currently publicly report the results of both measures for a large cohort of hospitals. In addition, both measures include a large number of admissions per hospital and therefore have sufficiently large sample sizes for most hospitals to support adequate reliability of stratified calculations. As a first step, in the interest of simplicity and to minimize confusion for hospitals, we are planning to provide confidential feedback reports for the Pneumonia Readmission measure only, using both methodologies.

For the future, we are considering: (1) Expanding our efforts to provide stratified data in hospital confidential feedback reports for other measures; (2) including other social risk factors beyond dual-eligible status in hospital confidential feedback reports; and (3) eventually, making stratified data publicly available on the *Hospital Compare* website, as mentioned in previous rules, to allow consumers and other stakeholders to view critical information about the care and outcomes of subgroups of patients with social risk factors. We believe the stratified results will provide hospitals with information that could illuminate disparities in care or outcome, which could subsequently be targeted through quality improvement efforts. We further believe that public display of this information could drive consumer choice and spark additional improvement efforts. A CMS contractor will convene a Technical Expert Panel (TEP) in the spring of 2018 to solicit feedback from stakeholders on approaches to consider for stratification for the Hospital IQR Program. We anticipate receiving additional input from hospitals when they receive confidential feedback reports of the stratified results and will encourage stakeholders to submit comments during this process. We are also considering how these methodologies may be adapted to apply to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

We are inviting public comments on these considerations for the future.

11. 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. 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 description above. In accordance with the statute, the FY 2019 payment determination will begin the fifth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. 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. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/*. The annual update of electronic clinical quality measure (eCQM) specifications and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*. Hospitals must register and submit quality data through the secure portion of the QualityNet website. There are safeguards in place in accordance with the HIPAA Security

Rule to protect patient information submitted through this website.

b. 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.

c. 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.

d. Reporting and Submission Requirements for eCQMs

For a discussion of our previously finalized eCQMs and policies, 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), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493).

In this proposed rule, we are: Clarifying measure logic used in eCQM development; proposing to extend previously established eCQM reporting and submission requirements for the CY 2019 reporting period/FY 2021 payment determination; and proposing to require hospitals to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination. These matters are discussed in detail below.

(1) Clarification of the Measure Logic Used in eCQM Development—Transition to Clinical Quality Language (CQL)

Although the measure logic, which represents the lines of logic that comprise a single AND/OR statement composing each population, used in eCQM development is not generally specified through notice and comment rulemaking, we wish to notify the public that all eCQM specifications published in CY 2018 for the CY 2019 reporting period/FY 2021 payment determination and subsequent years (beginning with the Annual Update that will be published in Spring 2018 and for implementation in CY 2019) will use the Clinical Quality Language (CQL). CQL is a Health Level Seven (HL7) International standard [320] and aims to unify the expression of logic for eCQMs and Clinical Decision Support (CDS).[321] CQL provides the ability to better express logic defining measure populations to improve the accuracy and clarity of eCQMs. In addition, CQL is a high-level authoring language that is intended to be human-readable and allows measure developers to express data criteria and represent it in a manner suitable for language processing.

Prior to CY 2017, eCQM logic was defined by ''Quality Data Model (QDM) Logic,'' an information model that defines relationships between patients and clinical concepts in a standardized format to enable electronic quality performance measurement.[322] We believe that compared to CQL, QDM logic is more complex and difficult to compute. QDM logic limits a measure developer's ability to express the type of comparisons needed to truly evaluate outcomes of care because QDM logic cannot request patient results that indicate outcomes and assess improvement over time; in contrast, CQL's mathematical expression logic allows this type of comparison over time and is independent of the model.[323] Moreover, CQL: (1) Offers improved expressivity; (2) is more precise/unambiguous; (3) can share logic between measures; (4) allows for measure logic to be shared with CDS tools; (5) can be used with multiple information data models (for example, QDM, Fast Healthcare Interoperability Resources (FHIR) [324]); and (6) simplifies calculation engine implementation.[325] CQL replaces the logic expressions defined in the QDM, and QDM (beginning with v5.3 [326]) includes only the conceptual model for defining the data elements.

Measure developers successfully tested CQL for expressing eCQMs from 2016 through 2017.[327] Based on the results, the Measure Authoring Tool (MAT) [328] and the Bonnie [329] tool have been updated to use CQL. We believe replacing the measure logic used in eCQM development from QDM to CQL will enable measure developers to engineer more precise, more interoperable measures that interface with CDS tools, which in turn, will result in availability of better measures of patient outcomes for use in the Hospital IQR Program and other CMS programs. We note that utilization of CQL for the eCQMs currently available for reporting in the Hospital IQR Program measure set would not affect the intent of the measure, the numerator, denominator, or any measure exclusions or exceptions.

For additional information about the CQL transition and its impact on eCQM development, we refer readers to the eCQI Resource Center website at: *https://ecqi.healthit.gov/cql*.

[320] Additional details about HL7 are available at: *http://www.hl7.org/about/index.cfm?ref=nav*. In addition, readers may learn more under ''Where can I find more information on CQL'' on the eCQI Resource Center website at: *https://ecqi.healthit.gov/cql*.

[321] Additional details about CDS is available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/cds*.

[322] Additional details about QDM Logic are available at: *https://ecqi.healthit.gov/qdm*.

[323] Additional details about how CQL Logic is Different from QDM Logic are available at: *https://ecqi.healthit.gov/qdm/qdm-Qs%26As#QualityDataModelQDMforusewithClinicalQualityLanguageCQL*.

[324] FHIR, developed by Health Level Seven International (HL7), is designed to enable information exchange to support the provision of healthcare in a wide variety of settings. The specification builds on and adapts modern, widely used RESTful practices to enable the provision of integrated healthcare across a wide range of teams and organizations. Additional information available at: *http://hl7.org/fhir/overview-dev.html*.

[325] Additional details on the benefits of Clinical Quality Language (CQL) are available at: *https://ecqi.healthit.gov/system/files/Benefits_of_CQL_May2017-508.pdf*.

[326] Additional details about QDM v5.3 available at: *https://ecqi.healthit.gov/qdm/qdm-news-0/now-available-quality-data-model-qdm-v53*.

[327] Additional details about the Timeline for the Transition to CQL are available at: *https://ecqi.healthit.gov/cql*.

[328] The Measure Authoring Tool (MAT) is a web-based tool that allows measure developers to author electronic Clinical Quality Measures (eCQMs). Using the tool, authors create Clinical Quality Language (CQL) expressions, which have the conceptual portion of the Quality Data Model (QDM) as their foundation (*https://www.emeasuretool.cms.gov/*).

[329] Bonnie is a tool for testing electronic clinical quality measures (eCQMs) designed to support streamlined and efficient pre-testing of eCQMs, particularly those used in the CMS quality programs (*https://bonnie.healthit.gov/*).

(2) Reporting and Submission Requirements for eCQMs for the CY 2019 Reporting Period/FY 2021 Payment Determination

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38361), we finalized eCQM reporting and submission requirements such that hospitals are 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. In this proposed rule, in alignment with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), we are proposing to extend the same eCQM reporting and submission requirements, such that hospitals would be required to report one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2019 reporting period/FY 2021 payment determination. We believe continuing the same eCQM reporting and submission requirements is appropriate because doing so continues to offer hospitals reporting flexibility and does not increase the information collection burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQM documentation and reporting. We also refer readers to section VIII.D.9. of the preamble of this proposed rule where similar proposals are discussed for the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs).

We are inviting public comment on our proposal.

(3) Changes to the Certification Requirements for eCQM Reporting Beginning With the CY 2019 Reporting Period/FY 2021 Payment Determination

In the FY 2018 IPPS/LTCH PPS final rule, we finalized a policy to allow flexibility for hospitals to use the 2014 Edition certification criteria, the 2015 Edition certification criteria, or a combination of both for the CY 2018 reporting period/FY 2020 payment determination only (82 FR 38388). This was a change to the policy previously finalized in the FY 2017 IPPS/LTCH PPS final rule that required hospitals to use the 2015 Edition certification criteria for CEHRT for the CY 2018 reporting period/FY 2020 payment determination and subsequent years (81 FR 57171).

In this proposed rule, to align with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), for the Hospital IQR Program, we are proposing to require hospitals to use only the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination. We refer readers to section VIII.D.3. of the preamble of this proposed rule in which the Medicare and Medicaid Promoting Interoperability Programs discuss more broadly the reasons for and benefits of requiring hospitals to use the 2015 Edition certification criteria for CEHRT, beginning with the CY 2019 reporting period/FY 2021 payment determination. There are certain functionalities in the 2015 Edition of certified electronic health record technology that were not available in the 2014 Edition that we believe will increase interoperability and the flow of information between providers and patients.

In addition, as we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38387 through 38388), specifically as to eCQM reporting, the 2015 Edition includes updates to standards for structured data capture as well as data elements in the common clinical data set which can be captured in a structured format. We continue to believe the use of relevant, up-to-date, standards-based structured data capture with an EHR certified to the 2015 Edition supports electronic clinical quality measurement.

The 2015 Edition certification criteria (that make up CEHRT) within the certification testing process includes features that are designed to improve the functionality and quality of eCQM data.[330] Specifically, systems must demonstrate they can import and allow a user to export one or more QRDA files. This allows systems to share files and extract data for reporting into another system or send to another system. In addition, testing coverage is much more robust; all measures have >80 percent of test pathways tested in the test bundle with most >95 percent. In addition, the 2015 Edition includes a revised requirement that products must be able to export data from one patient, a set of patients, or a subset of patients, which is responsive to health care provider feedback that their data is unable to carry over from a previous EHR. The 2014 Edition did not include a requirement that the vendor allow the provider to export the data themselves. In the 2015 Edition, the provider has the autonomy to export data themselves without intervention by their vendor, resulting in increased interoperability and data exchange between the two Editions. This includes a new function that supports increased patient access to their health information through email transmission. The increased interoperability in this requirement provides patients more control of their health data to inform the decisions that they make regarding their health.

The 2015 Edition certification criteria for CEHRT also includes optional certification criteria and program specific testing which can also support electronic clinical quality reporting. The filter criteria ensure a product can filter an electronic file based on demographics like sex or race, based on provider or site characteristics like TIN/NPI, and based on a diagnosis or problem. The testing for this function checks that patients are appropriately aggregated and calculated for this new function which supports flexibility, specificity, and more robust analysis of eCQM data. Finally, the 2015 Edition provides optional testing to CMS requirements for reporting, such as form and manner specifications and implementation guides. For these reasons, in this proposed rule, we are proposing to require hospitals to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination.

We note that the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination (80 FR 62873 through 62875), such that hospitals participating in both the Hospital IQR Program and the Medicare and Medicaid Promoting Interoperability Programs already would be required to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination.

We are inviting public comment on our proposal to require hospitals to use the 2015 Edition certification criteria for CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination.

e. Electronic Submission Deadlines

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) for our previously

[330] For CEHRT definition, see 42 CFR 495.4. For additional details about the updates to the 2015 Edition, we refer readers to ONC's Common Clinical Data Set resource, available at: *https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-5.pdf.*

adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR Program and the Medicare Promoting Interoperability Program (previously known as the Medicare EHR Incentive Program). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we established eCQM submission deadlines for the Hospital IQR Program. We are not proposing any changes to the eCQM submission deadlines in this proposed rule.

f. Sampling and Case Thresholds

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 our sampling and case threshold policies in this proposed rule.

g. 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 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. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), we finalized refinements to the three questions of the Pain Management measure in the HCAHPS Survey (now referred to as the Communication About Pain measure). We are not proposing any changes to the HCAHPS Survey administration and submission requirements in this proposed rule.

h. Data Submission Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. We are not proposing any changes to those requirements in this proposed rule; however, we refer readers to sections VIII.A.5.a. and VIII.A.5.b.(1) of the preamble of this proposed rule, in which we are proposing to remove two structural measures from the Hospital IQR Program. If our proposals to remove two structural measures are adopted, no structural measures would remain in the Hospital IQR Program and hospitals would not be required to submit any data for structural measures for the CY 2019 reporting period/FY 2021 payment determination or subsequent years.

i. Data Submission and Reporting Requirements for HAI Measures Reported via NHSN

For details on the data submission and reporting requirements for HAI measures reported via the CDC's NHSN website, 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 at: *http://www.QualityNet.org/*.

While we are not proposing any changes to these requirements, we refer readers to section VIII.A.5.b.(2)(b) of the preamble of this proposed rule, in which we are proposing to remove five HAI measures reported via NHSN from the Hospital IQR Program. If our proposals to remove these five measures are adopted, there would be no HAI measures reported via NHSN and hospitals would not be required to submit any data for HAI measures via NHSN for the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination or subsequent years. We note that the HCP measure remains in the Hospital IQR Program and will continue to be reported via NHSN. In addition, we note that the five HAI measures being proposed for removal in the Hospital IQR Program will still remain in the HAC Reduction Program. We refer readers to section IV.J. of the preamble of this proposed rule for more information about how those measures will be collected and validated under the HAC Reduction Program.

12. Validation of Hospital IQR Program Data

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years. The FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years that are still in effect. We refer readers to 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), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712) for detailed information on the modifications to these processes finalized for the FY 2016, FY 2017, and FY 2018 payment determinations and subsequent years. We are not proposing any changes to the existing processes for validation of either eCQM or chart-abstracted measure data in this proposed rule.

b. Existing Processes for Validation of Hospital IQR Program eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), we finalized updates to the validation procedures in order to incorporate a process for validating eCQM data 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 also refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), in which we finalized several proposals regarding 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. We are not proposing any changes to the existing processes for validation of Hospital IQR Program eCQM data in this proposed rule.

c. Existing Process for Chart-Abstracted Measures Validation

In the FY 2015 IPPS/LTCH PPS final rule, we stated that we rely on hospitals to request an educational review or appeal cases to identify any potential CDAC or CMS errors (79 FR 50260). We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38403) for more details on the formalized Educational Review Process for Chart-Abstracted Measures Validation. We are not proposing any changes to the validation of chart-abstracted measures, including the educational review process.

While we are not proposing any changes to our previously established validation procedures in this proposed rule, we refer readers to: (1) Section VIII.A.5.b.(8) of the preamble of this proposed rule, in which we are

proposing to remove three clinical process of care measures beginning with the CY 2019 reporting period/FY 2021 payment determination, and one clinical process of care measure beginning with the CY 2020 reporting period/FY 2022 payment determination; and (2) section VIII.A.5.b.(2)(b) of the preamble of this proposed rule, in which we are proposing to remove five Hospital-Acquired Infection (HAI) chart-abstracted measures from the Hospital IQR Program beginning with the CY 2019 reporting period/FY 2021 payment determination. If our proposals to remove these measures are adopted, only two chart-abstracted clinical process of care measures would remain in the Hospital IQR Program that would require validation for the FY 2022 payment determination (ED–2 and Sepsis measures), and only one chart-abstracted clinical process of care measure would remain in the program that would require validation for the FY 2023 payment determination and subsequent years (Sepsis measure). As our validation processes remain unchanged, we will continue to sample up to 8 cases for each selected chart-abstracted clinical process of care measure. We plan to evaluate our existing validation scoring methodology to ensure that there will be no significant impact to the estimated reliability (ER) of Hospital IQR Program chart-abstracted data validation activities despite any measure removals.

In addition, the CY 2019 reporting period/FY 2021 payment determination would be the last year for which validation would occur under the Hospital IQR Program with respect to the CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI measures, if our proposed measure removals are finalized in section VIII.A.5.b.(2)(b) of the preamble of this proposed rule. Beyond the FY 2021 payment determination, we intend for validation of those measures to occur under the HAC Reduction Program, as further discussed in section IV.J.4.e. of the preamble of this proposed rule.

13. 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 the DACA requirements in this proposed rule.

14. Public Display Requirements

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), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) 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*, but on occasion are reported on other CMS websites such as: *https://data.medicare.gov*.

We are not proposing any changes to the public display requirements in this proposed rule. However, we note that in section VIII.A.10. of the preamble of this proposed rule, we discuss our efforts to provide stratified data by patient dual eligibility status in hospital confidential feedback reports and considerations to make stratified data publicly available on the *Hospital Compare* website in the future.

15. 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 the reconsideration and appeals procedures in this proposed rule.

16. 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 the ECE policy in this proposed rule.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program strives to put patients first by ensuring they, along with their clinicians, are empowered to make decisions about their own health care using data-driven insights that are increasingly aligned with meaningful quality measures. To this end, we support technology that reduces burden and allows clinicians to focus on providing high quality health care to their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when participating in CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the PCHQR Program incentivizes PCHs to improve their health care quality and value, while giving patients the tools and information needed to make the best decisions.

For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425).

In this proposed rule, we are proposing a number of new policies for the PCHQR Program. We developed these proposals after conducting an overall review of the program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of the preamble of this proposed rule. The proposals reflect our efforts to ensure that the PCHQR

Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing the following: (1) The reporting burden associated with submitting/reporting quality measures; (2) the burden associated with complying with other programmatic requirements; and/or (3) the burden associated with compliance with other Federal and/or State regulations (if applicable). In addition, we aim to reduce beneficiary confusion by reducing duplicative reporting, thereby streamlining the process of analyzing publicly reported quality measures data. They also reflect our efforts to improve the usefulness of the data that we publicly report in the PCHQR Program, which are guided by the following two goals: (1) To improve the usefulness of CMS quality program data by providing providers with adequate measure information from one program; and (2) to improve consumer understanding of the data publicly reported on a *Compare* other website by eliminating the reporting of duplicative measure data in more than one program that applies to the same provider setting.

2. Factors for Removal and Retention of PCHQR Program Measures

a. Background and Current Measure Removal Factors

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), we adopted policies for measure retention and removal. We generally retain measures from the previous year's PCHQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. We adopted the following measure removal factors [331] for the PCHQR Program, which are based on factors adopted for the Hospital IQR Program (80 FR 49641 through 49642):

- Factor 1. Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);
- Factor 2. A measure does not align with current clinical guidelines or practice;
- Factor 3. The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4. Performance or improvement on a measure does not result in better patient outcomes;
- Factor 5. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- Factor 7. It is not feasible to implement the measure specifications.

For the purposes of considering measures for removal from the program, we consider a measure to be ''topped-out'' if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10.

b. Measure Retention Factors

We have also recognized that there are times when measures may meet some of the outlined criteria for removal from the program, but continue to bring value to the program. Therefore, we have adopted the following factors for consideration in determining whether to retain a measure in the PCHQR Program, which also are based on factors established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

c. Proposed New Measure Removal Factor

We are proposing to adopt an additional factor to consider when evaluating potential measures for removal from the PCHQR measure set: Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program.

As we discussed in section I.A.2. of the preamble of this proposed rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the PCHQR measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Provider and clinician information collection burden and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the cost to CMS associated with the program oversight of the measure including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other Federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools we need to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the PCHQR Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the PCHQR Program is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the PCHQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting

[331] We note that we previously referred to these factors as ''criteria'' (for example, 81 FR 57182 through 57183); we now use the term ''factors'' in order to align the PCHQR Program terminology with the terminology we use in other CMS quality reporting and pay for performance value-based purchasing programs.

burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal factor, ''the costs associated with a measure outweigh the benefit of its continued use in the program,'' beginning with the effective date of the FY 2019 IPPS/LTCH PPS final rule.

3. Retention and Proposed Removal of Previously Finalized Quality Measures for PCHs Beginning With the FY 2021 Program Year

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program year and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50847), we finalized one new quality measure for the FY 2015 program year and subsequent years and 12 new quality measures for the FY 2016 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280), we finalized one new quality measure for the FY 2017 program year and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49719), we finalized three new Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) measures for the FY 2018 program year and subsequent years, and finalized the removal of six previously finalized measures for fourth quarter (Q4) 2015 discharges and subsequent years. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57183 through 57184), for the FY 2019 program year and subsequent years, we finalized one additional quality measure and updated the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure. In the FY 2018 IPPS/LTCH PPS final rule, we finalized four new quality measures (82 FR 38414 through 38420), for the FY 2020 program year and subsequent years, and finalized the removal of three previously finalized measures (82 FR 38412 through 38414).

b. Proposed Removal of Measures From the PCHQR Program Beginning With the FY 2021 Program Year

We are proposing to remove four web-based, structural measures from the PCHQR Program beginning with the FY 2021 program year because they are topped-out:

- Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382);
- Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384);
- Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and
- Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389).

We also are proposing to apply the newly proposed measure removal factor to two National Healthcare Safety Network (NHSN) chart-abstracted measures and, if that factor is finalized, to remove both measures from the PCHQR Program beginning with the FY 2021 program year because we have concluded that the costs associated with these measures outweigh the benefit of their continued use in the program.

- NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138); and
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139).

(1) Proposed Removal of Web-Based Structural Measures

We are proposing to remove the following web-based, structural measures beginning with the FY 2021 program year because they are topped-out: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389). We first adopted these measures for the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50844). We refer readers to that rule for a detailed discussion of the measures.

Based on an analysis of data from January 1, 2015 through December 31, 2016, we have determined that these three measures meet our topped-out criteria. This analysis evaluated data sets and calculated the 5th, 10th, 25th, 50th, 75th, 90th, and 95th percentiles of national facility performance for each measure. For measures where higher values indicate better performance, the percent relative difference (PRD) between the 75th and 90th percentiles were obtained by taking their absolute difference divided by the average of their values and multiplying the result by 100. To calculate the truncated coefficient of variation (TCV), the lowest 5 percent and the highest 5 percent of hospital rates were discarded before calculating the mean and standard deviation for each measure.

The following criteria were applied to the results:

- For measures ranging from 0–100 percent, with 100 percent being best, national measure data for the 75th and 90th percentiles have a relative difference of <=5 percent, or for measures ranging from 0–100 percent, with 100 percent being the best, performance achieved by the median hospital is >=95 percent, and national measure data have a truncated coefficient of variation <=0.10.
- For measures ranging from 0–100 percent, with 0 percent being best, national measure data for the complement of the 10th and 25th percentiles have a relative difference of <=5 percent, or for measures ranging from 0–100 percent, with 0 percent being best, national measure data for the median hospital is <=5 percent, or for other measures with a low number indicating good performance, national measure data for the 10th and 25th percentiles have a relative difference of <=5 percent, and national measure data have a truncated coefficient of variation <=0.10.

The results for 2015 and 2016 are set out in the tables below.

TOPPED-OUT ANALYSIS RESULTS FOR PCHQR MEASURES (2015)

Measure	Mean	Median	75th Percentile	90th Percentile	Relative difference (%)	Topped-out
PCH–14	98.4	99.6	100	100	0	Yes
PCH–16	92.5	92.3	93.1	94.3	1.2	Yes
PCH–17	99.7	100	100	100	0	Yes
PCH–18	98.9	99.4	100	100	0	Yes

TOPPED-OUT ANALYSIS RESULTS FOR PCHQR MEASURES (2016)

Measure	Mean	Median	75th Percentile	90th Percentile	Relative difference (%)	Topped—out
PCH–14	99.8	100	100	100	0	Yes
PCH–16	96.8	96.8	97.3	97.4	0.1	Yes
PCH–17	99.4	99.6	100	100	0	Yes
PCH–18	99.0	100	100	100	0	Yes

Based on this analysis, we have concluded that these four measures are topped-out and, as discussed below, we believe that collecting PCH data on these measures does not further program goals.

We also believe that continuing to collect PCH data on these measures does not further program goals of improving quality, given that performance on the measures is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. We believe that these measures also do not meet the criteria for retention of an otherwise topped-out measure, as they: Do not align with the HHS and CMS policy goal to focus our measure set on outcome measures; do not align with measures used in other CMS programs; and do not support our efforts to develop electronic clinical quality measure reporting for PCHs. If we determine at a subsequent point in the future that PCH adherence to the aforementioned HHS and CMS policy goals, the aforementioned program efforts, and the standard of care established by the measure has unacceptably declined, we may propose to readopt these measures in future rulemaking.

We are inviting public comment on our proposal to remove these four measures from the PCHQR Program beginning with the FY 2021 program year.

(2) Proposed Removal of National Healthcare Safety Network (NHSN) Chart-Abstracted Measures

We are proposing to remove two measures from the PCHQR Program beginning with the FY 2021 program year if the measure removal factor ''the costs associated with the measure outweigh the benefit of its continued use in the program'' proposed for adoption in section VIII.B.2.c. of the preamble of this proposed rule, is finalized because we have concluded that the costs associated with these measures outweigh the benefit of their continued use in the PCHQR Program. These measures are: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138); and (2) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139). We first adopted the CAUTI and CLABSI measures for the FY 2014 program year in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53557 through 53559); we refer readers to this rule for a detailed discussion of the measures.

As discussed in section I.A.2. of the preamble of this proposed rule, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We continue to believe the CAUTI and CLABSI measures provide important data for patients and hospitals in making decisions about care and informing quality improvement efforts. However, we believe that removing these measures in the PCHQR Program will reduce program costs and complexity. We believe the costs, coupled with the high technical and administrative burden on PCHs, associated with collecting and reporting this measure data outweigh the benefits to continued use in the program. As a result of these costs, it has become difficult to publicly report these measures due to the low volume of data produced and reported by the small number of facilities participating in the PCHQR Program and the corresponding lack of an appropriate methodology to publicly report this data. Consequently, we have been unable to offer beneficiaries the benefit of pertinent information on how these measures assess hospital-acquired infections and impact patient safety.

As we state in section I.A.2. of the preamble of this proposed rule, we strive to ensure that patients are empowered to make decisions about their health care along using information from data-driven insights. We continue to believe that these measures evaluate important aspects of patient safety. However, as discussed earlier, we believe the high costs, reporting burden, and difficulties associated with publicly reporting this data for use by patients in making decisions about their care outweigh the benefit associated with the measures' continued use in the PCHQR Program. Therefore, if our proposal to adopt the new measure removal factor described in section VIII.B.2.c. of the preamble of this proposed rule is finalized as proposed, we are proposing that under that factor, we would remove the CAUTI and CLABSI measures from the PCHQR Program beginning with the FY 2021 program year.

We are inviting public comment on our proposal to remove these two measures from the PCHQR Program beginning with the FY 2021 program year.

4. Proposed New Quality Measures Beginning With the FY 2021 Program Year

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we take many principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In section I.A.2. of the preamble of this proposed rule, we also discuss our Meaningful Measures Initiative, and its relation to how we will assess and select quality measures for the PCHQR Program.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

Using these principles for measure selection in the PCHQR Program, we are

proposing one new measure, described below.

b. Proposed New Quality Measure Beginning With the FY 2021 Program Year: 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188)

In an effort to expand the PCHQR measure set to include measures that are less burdensome to report to CMS, but provide valuable information for beneficiaries, we are proposing to adopt the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) for the FY 2021 program year and subsequent years. This measure meets the requirement under section 1866(k)(3)(A) of the Act that measures specified for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act (currently the NQF). This measure aligns with recent initiatives to incorporate more outcome measures in quality reporting programs. This measure also aligns with the Promote Effective Communication and Coordination of Care domain of our Meaningful Measures Initiative,[332] and would fill an existing gap area of risk-adjusted readmission measures in the PCHQR Program.

In compliance with section 1890A(a)(2) of the Act, the proposed measure was included on a publicly available document entitled ''2017 Measures under Consideration Spreadsheet,'' [333] a list of quality and efficiency measures under consideration for use in various Medicare programs, and was reviewed by the Measures Application Partnership (MAP) Hospital Workgroup.

(1) Background

Cancer is the second leading cause of death in the United States, with nearly 600,000 cancer-related deaths expected this year. It is estimated roughly 1.7 million Americans will be diagnosed with cancer in 2016, and the number of Americans living with a cancer diagnosis reached nearly 14.5 million in 2014.[334] Cancer disproportionately affects older Americans, with 86 percent of all cancers diagnosed in people 50 years of age and older.[335] It is now the leading cause of death among adults age 40 to 79 years nationwide, and the leading cause of death among all adults in 21 States.[336] Oncology care contributes greatly to Medicare spending, and accounted for an estimated $125 billion in health care spending in 2010.[337] This figure is projected to rise to between $173 billion and $207 billion by 2020.[338] A 2012 audit from the US Government Accountability Office (GAO) revealed that the estimated differences in Medicare payment between PCHs and local PPS teaching hospitals varied greatly across the PCHs; with the largest payment difference at 90.9 percent and the smallest payment difference at 6.7 percent. Overall, the difference between the amount Medicare paid PCHs and the estimated amount Medicare would have paid PPS hospitals for treating comparable cancer patients suggests that Medicare would have saved approximately $166 million in 2012.[339] Further, GAO calculated that, if PCHs were paid for outpatient services in the same way as PPS teaching hospitals, Medicare would have saved approximately $303 million in 2012.[340]

Given the current and projected increases in cancer prevalence and costs of care, it is essential that health care providers look for opportunities to lower the costs of cancer care. Reducing readmissions after hospital discharge has been proposed as an effective means of lowering health care costs and improving the outcomes of care.[341] Research suggests that between 9 percent and 48 percent of all hospital readmissions are preventable, owing to inadequate treatment during the patient's original admission or after discharge.[342] It is estimated that all-cause, unplanned readmissions cost the Medicare program $17.4 billion in 2004.[343] Unnecessary hospital readmissions also negatively impact cancer patients by compromising their quality of life, placing them at risk for health-acquired infections, and increasing the costs of their care.[344] Furthermore, unplanned readmissions during treatment can delay treatment completion and, potentially, worsen patient prognosis.[345]

Preventing these readmissions improves the quality of care for cancer patients. Existing studies in cancer patients have largely focused on postoperative readmissions, reporting readmission rates of between 6.5 percent and 25 percent.[346] One study noted that surgical cancer patients were most often readmitted for surgical complications, while nonsurgical patients were typically readmitted for the same condition treated during the index admission.[347] Together, these studies suggest that certain readmissions in cancer patients are preventable and should be routinely measured for purposes of quality improvement and accountability.

(2) Overview of Measure

Readmission rates have been developed for pneumonia, acute myocardial infarction, and heart failure. However, the development of validated readmission rates for cancer patients has lagged. In 2012, the Comprehensive Cancer Center Consortium for Quality Improvement, or C4QI (a group of 18 academic medical centers that collaborate to measure and improve the quality of cancer care in their centers), began development of a cancer-specific unplanned readmissions measure: 30-Day Unplanned Readmissions for Cancer Patients. This measure incorporates the unique clinical characteristics of oncology patients and results in readmission rates that more accurately reflect the quality of cancer care delivery, when compared with broader readmissions measures. Likewise, this measure addresses gaps in existing readmissions measures (such as the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) stewarded by CMS) related to the evaluation of hospital readmissions associated cancer patients. The 30-Day Unplanned Readmissions for Cancer

[332] Overview of the CMS Meaningful Measures Initiative available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html.*

[333] 2017 Spreadsheet of Measures Under Consideration. Available at: *http://www.qualityforum.org/Show_Content.aspx?id=30279.*

[334] NIH's National Cancer Institute Statistics. Available at: *https://www.cancer.gov/about-cancer/understanding/statistics.*

[335] American Cancer Society. Cancer facts and figures 2016. 2016. Available at: *http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf.*

[336] Siegel RL, Miller KD, Jemal A. Cancer statistics, 2016. *CA Cancer J Clin.* 2016;66(1):7–30.

[337] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010–2020. *J Natl Cancer Inst.* 2011;103(2):117–128.

[338] Ibid.

[339] US Government Accountability Office. ''Medicare Payments to Certain Cancer Hospitals.'' Accessed on March 9, 2018. Available at: *https://www.gao.gov/modules/ereport/handler.php?1=1&path=/ereport/GAO–15–404SP/data_center_savings/Health/19._Medicare_Payments_to_Certain_Cancer_Hospitals.*

[340] Ibid.

[341] Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. *Arch Intern Med.* 2000;160(8):1074–108.

[342] Ibid.

[343] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med.* 2009;360(14):1418–1428.

[344] Ibid.

[345] Ibid.

[346] Rochefort MM, Tomlinson JS. Unexpected readmissions after major cancer surgery: an evaluation of readmissions as a quality-of-care indicator. *Surg Oncol Clin N Am.* 2012;21(3):397–405, viii.

[347] Ji H, Abushomar H, Chen XK, Qian C, Gerson D. All-cause readmission to acute care for cancer patients. *Healthc Q.* 2012;15(3):14–16.

Patients measure can be used by PCHs to inform their quality improvement efforts. Through adoption in the PCHQR Program, it can increase transparency around the quality of care delivered to patients with cancer.

The 30-Day Unplanned Readmissions for Cancer Patients measure is NQF-endorsed (NQF #3188). The MAP Hospital Workgroup reviewed this measure on December 14, 2017 and supported the inclusion of this measure in the PCHQR Program. The MAP acknowledged that this measure is fully developed and tested and further noted this measure fills a current gap in the PCHQR Program by addressing unplanned readmissions of cancer patients.[348] [349]

The proposed readmission measure fits within the Promote Effective Communication and Coordination of Care measurement domain (categorical area), and specifically applies to the associated clinical topic of ''Admissions and Readmissions to Hospitals'' of our Meaningful Measures Initiative. This measure is intended to assess the rate of unplanned readmissions among cancer patients treated at PCHs and to support improved care delivery and quality of life for this patient population. By providing an accurate and comprehensive assessment of unplanned readmissions within 30 days of discharge, PCHs can better identify and address preventable readmissions. Through routine monitoring of these performance data by PCHs, this measure can be used to improve patient outcomes and quality of care.

(3) Data Sources

The proposed 30-Day Unplanned Readmissions for Cancer Patients measure is claims-based. Therefore, PCHs would not be required to submit any new data for purposes of reporting this measure. We are proposing that we would calculate this measure on a yearly basis using Medicare administrative claims data. Specifically, we are proposing that the data collection period for each program year would span from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Therefore, for the FY 2021 program year, we would calculate measure rates using PCH claims data from July 1, 2018 through June 30, 2019.

We assessed the measure's reliability, and set a minimum case count of 50 index admissions (25 per subset) per PCH. There were 3,502 facilities [350] included in the 100 split-half simulations for CY 2013 through CY 2015. In our reliability assessment, we examined the reliability of the measure by testing the hypothesis that the mean S–B statistic from each year was greater than 0.5. The S–B statistic allows us to project what the reliability would be if the entire sample were used instead of the split sample.

Overall, the consistent calculations between the two data randomly-split subsets for each period provided evidence that performance variations between PCHs were attributable to hospital-level factors, rather than patient-level factors. Regarding the validity of this measure, global sensitivity and specificity scores of 0.879 and 0.896, respectively, confirmed the validity of the Type of Admission/Visit reported via the UB–04 Uniform Bill Locator 14 (Claim Inpatient Admission Type Code [351] in the Medicare SAF) to accurately identify planned and unplanned readmissions, as validated by chart review. Together, these statistics indicate that there are opportunities to utilize this measure to reduced unplanned readmissions in cancer patients, making it useful for performance improvement and public reporting. Additional details on the testing results for this measure are provided in the testing attachment, which is available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=86089*.

(4) Measure Calculation

This outcome measure utilizes claims data to demonstrate the rate at which adult cancer patients have unplanned readmissions within 30 days of discharge from an eligible index admission. The numerator includes all eligible unplanned readmissions to the PCH within 30 days of the discharge date from an index admission to the PCH that is included in the measure denominator. The denominator includes inpatient admissions for all adult Medicare fee-for-service (FFS) beneficiaries where the patient is discharged from a short-term acute care hospital (PCH, short-term acute care PPS hospital, or CAH) with a principal or secondary diagnosis (that is, not admitting diagnosis) of malignant cancer within the defined measurement period. The measure excludes readmissions for patients readmitted for chemotherapy or radiation therapy treatment or with disease progression. The measure will be calculated as the numerator divided by the denominator. Measure specifications for the proposed measure can be accessed on the NQF's website at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=86089*.

(5) Cohort

This measure includes inpatient admissions for all adult Medicare FFS beneficiaries where the patient is discharged from a short-term acute care hospital (PCH, short-term acute care PPS hospital, or CAH) with a principal or secondary diagnosis (that is, not admitting diagnosis) of malignant cancer within the defined measurement period. Additional methodology and measure development details are available on the NQF's website at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=86089*.

(6) Risk Adjustment

This measure is risk-adjusted based on a comparison of observed versus expected readmission rates. Logistic regression analysis is used to estimate the probability of an unplanned readmission, based on the measure specifications and risk factors described herein. The probability of unplanned readmission is then summed over the index admissions for each hospital to calculate the *expected* unplanned readmission rate. Subsequently, the actual or *observed* unplanned readmissions for each hospital are summed and used to calculate the ratio of *observed* unplanned readmissions to *expected* unplanned readmissions for each hospital. Each hospital's ratio was then multiplied by the national or standard unplanned readmissions rate to generate the risk-adjusted *30-Day Unplanned Readmissions for Cancer Patients* rate (as specified in the following formula):

[348] 2018 Considerations for Implementing Measures Draft Report-Hospitals. Available at: *http://www.qualityforum.org/Show_Content.aspx?id=30279*.

[349] 2017–2018 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[350] We note that hospital testing occurred prior to our proposal for PCHQR Program inclusion. As such, the sample size is far greater than the number of applicable PCHs for which implementation this measure is being proposed for use to ensure data reliability.

[351] Claim Inpatient Admission Type Code available at: *https://www.resdac.org/cms-data/variables/Claim-Inpatient-Admission-Type-Code*.

$$Risk - Adjusted\ Rate = \frac{observed\ rate}{expected\ rate} \times national\ or\ standard\ rate$$

We are inviting public comment on our proposal to adopt the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) for the FY 2021 program year and subsequent years.

c. Summary of Previously Finalized and Proposed PCHQR Program Measures for the FY 2021 Program Year and Subsequent Years

The table below summarizes what the PCHQR Program measure set would look like for the FY 2021 program year if we finalized our measure removal proposals and our proposal to adopt the 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188):

FY 2021 PCHQR Program Measure Set if Proposals To Remove Four Measures and Adopt a New Readmissions Measure Are Finalized

Short name	NQF No.	Measure name
Safety and Healthcare-Associated Infection (HAI)		
Colon and Abdominal Hysterectomy SSI.	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery].
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.
HCP	0431	National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel.
Clinical Process/Oncology Care Measures		
N/A	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology.
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life.
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice.
Intermediate Clinical Outcome Measures		
EOL–ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life.
EOL–3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days.
Patient Engagement/Experience of Care		
HCAHPS	0166	HCAHPS.
Clinical Effectiveness Measure		
EBRT	1822	External Beam Radiotherapy for Bone Metastases.
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
N/A *	3188	30-Day Unplanned Readmissions for Cancer Patients.

* Measure proposed for adoption for the FY 2021 program year and subsequent years.

5. Accounting for Social Risk Factors in the PCHQR Program

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[352] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing

[352] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

programs.[353] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[354] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[355] allowing further examination of social risk factors in outcome measures.

In the FY 2018/CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

6. Possible New Quality Measure Topics for Future Years

a. Background

As discussed in sections section I.A.2. of the preamble of this proposed rule, we have begun analyzing our programs' measures using the framework we developed for the Meaningful Measures Initiative. We have also discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), the FY 2016 IPPS/LTCH PPS final rule (80 FR4979), the FY 2017 IPPS/LTCH PPS final rule (81 FR 25211), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38421 through 38423). Specifically, we discussed public comment and suggestions for measure topics addressing: (1) Making care affordable; (2) communication and care coordination; and (3) working with communities to promote best practices of healthy living. In addition, in the FY 2018 IPPS/LTCH PPS final rule, we welcomed public comment and specific suggestions for measure topics that we should consider for future rulemaking, including considerations related to risk adjustment and the inclusion of social risk factors in risk adjustment for any individual performance measures.

In this proposed rule, we are again seeking public comment on the types of measure topics we should consider for future rulemaking. We also are seeking public comment on two measures for potential future inclusion in the PCHQR Program:

- Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790); and
- Shared Decision Making Process (NQF #2962).

We discuss these measures and measurement topic areas in more detail below.

b. Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790)

The Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790) measure is an outcome measure. It assesses postoperative complications and operative mortality, which are important negative outcomes associated with lung cancer resection surgery. Specifically, the measure assesses the number of patients 18 years of age or older undergoing elective lung resection (Open or video-assisted thoracoscopic surgery (VATS) wedge resection, segmentectomy, lobectomy, bilobectomy, sleeve lobectomy, pneumonectomy) for lung cancer who developed one of the listed postoperative complications described in the measure's specifications.[356] The lung cancer resection risk model utilized in this measure identifies predictors of these outcomes, including patient age, smoking status, comorbid medical conditions, and other patient characteristics, as well as operative approach and the extent of pulmonary resection. Knowledge of these predictors informs clinical decision-making by

[353] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[354] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[355] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

[356] Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (NQF #1790) Measure Specifications. Available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*.

enabling physicians and patients to understand the associations between individual patient characteristics and outcomes. Further, with continuous feedback of performance data over time, knowledge of these predictors and their relationship with patient outcomes also will foster quality improvement.

This measure aligns with recent initiatives to incorporate more outcome measures in quality reporting programs. This measure also aligns with the Promote Effective Prevention and Treatment of Chronic Disease domain of our Meaningful Measures Initiative,[357] and would fill an existing gap area of risk-adjusted mortality measures in the PCHQR Program. This measure has not yet been reviewed by the MAP. Additional information on this measure is available at: *http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C*, under the ''Candidate Consensus Standards Review: Phase-1'' section.

We are requesting public comment on the possible inclusion of this measure in future years of the program.

c. Shared Decision-Making Process (NQF #2962)

The Shared Decision-Making Process (NQF #2962) measure is a patient-reported outcome measure. This measure asks patients who had any of seven preference-sensitive surgical interventions to report on the interactions they had with their providers when the decision was made to have the surgery. Specifically, this measure assesses patient answers to four questions about whether three essential elements of shared decision-making: (1) Laying out options; (2) discussing the reasons to have the intervention and not to have the intervention; and (3) asking for patient input—were part of the patient's interactions with providers when the decision was made to have the procedure. When faced with a medical problem for which there is more than one reasonable approach to treatment or management, shared decision-making means providers should outline for patients that there is a choice to be made, discuss the pros and cons of the available options, and make sure that patients have input into the final decision. The result will be decisions that align better with patient goals, concerns, and preferences.

This measure aligns with recent initiatives to include patient-reported outcomes and experience of care into quality reporting programs, as well as to incorporate more outcome measures generally. This measure also aligns with the Strengthen Person and Family Engagement as Partners in Their Care domain of our Meaningful Measures Initiative,[358] and would fill an existing gap area of care aligned with the person's goals in the PCHQR Program. This measure has not yet been reviewed by the MAP. Additional information on this measure is available at: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=80842*.

We are requesting public comment on the possible inclusion of this measure in future years of the program.

d. Future Measurement Topic Areas

As discussed in section I.A.2. of the preamble of this proposed rule, we intend to review and assess the quality measures that we collect and score in our quality programs. As a part of the review process, we are continually evaluating the existing PCHQR measures portfolio and identifying gap areas for future measure adoption and/or development. In tandem with this portfolio evaluation, we have conducted a measure environmental scan. We believe that staying abreast of the cancer measurement environment and staying in communication with the cancer measure development community are vital to the ensure that the PCHQR Program measure portfolio remains aligned with current CMS and HHS goals. As a part of our efforts to include a comprehensive set of cancer measures in the PCHQR Program, we are currently assessing whether we should redefine the scope of new quality metrics we implement in the PCHQR Program in future years. Specifically, we are trying to determine whether the PCHQR Program would most benefit from the inclusion of more quality measures that examine general cancer care (that is, outcome measures that assess cancer care) or more measures that examine cancer-specific clinical conditions (such as prostate cancer, esophageal cancer, colon cancer, or uterine cancer).

We welcome public comment and specific suggestions on the inclusion of quality measures that examine general cancer care versus the inclusion of quality measures that examine cancer-specific clinical conditions in future rulemaking.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet website at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863*.

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.

8. 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 to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS website.

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 actually 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 2018 IPPS/LTCH PPS final rule (82 FR 38422 through 38424), we listed our finalized public display requirements for the FY 2020 program year.

[357] Overview of CMS ''Meaningful Measures'' Initiative available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html.*

[358] Ibid.

PREVIOUSLY FINALIZED PUBLIC DISPLAY REQUIREMENTS FOR THE FY 2020 PROGRAM YEAR

Summary of previously finalized public display requirements

Measures	Public reporting
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382).*	
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384).*	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).*	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).*	
• HCAHPS (NQF #0166)	2016 and subsequent years.
• CLABSI (NQF #0139).*	
• CAUTI (NQF #0138).*	Deferred.
• External Beam Radiotherapy for Bone Metastases (NQF #1822)	Beginning when feasible in 2017 and for subsequent years.

*Measure proposed for removal beginning with the FY 2021 program year.

We recognize the importance of being transparent with stakeholders and keeping them abreast of any changes that arise with the PCHQR set. As such, we provide a discussion of some recent changes affecting the timetable for the public displaying of data for specific PCHQR measures in the section below.

b. Proposed Deferment of Public Display of Four Measures

We adopted the Colon and Abdominal Hysterectomy SSI (NQF #0753) measure in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50839 through 50840) and the MRSA measure (NQF #1716), the CDI measure (NQF #1717) and the HCP measure (NQF #0431) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49715 through 49718).

At present, all PCHs are reporting Colon and Abdominal Hysterectomy SSI, MRSA, CDI, and HCP data to the NHSN under the PCHQR Program. However, performance data for these measures are new, and do not span a long enough measurement period to draw conclusions about their statistical significance at this point. Specifically, in 2016, the Centers for Disease Control and Prevention (CDC) announced that HAI data reported to NHSN for 2015 will be used as the new baseline, serving as a new ''reference point'' for comparing progress.[359] These current rebaselining efforts make year-to-year data comparisons inappropriate at this time. However, in FY 2019, we will have 2 years of comparable data to properly assess trends.[360] Therefore, we are proposing to delay the public reporting of data for the SSI, MRSA, CDI, and HCP measures until CY 2019.

We are inviting public comment on our proposal to delay public reporting of these four measures until CY 2019.

c. Clarification of Public Display of External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) Measure

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282 through 50283), we finalized that PCHs would begin reporting the External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) measure beginning with January 1, 2015 discharges and for subsequent years. We finalized that PCHs would report this measure to us via a CMS web-based tool on an annual basis (July 1 through August 15 of each respective year). Lastly, we finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57192) that we would begin to display the measure data during CY 2017, and that we would use a CMS website and/or our applicable Listservs to announce the exact timeframe.

We publicly reported data on this measure in December of 2017, and that data can be accessed on *Hospital Compare* at: *https://www.medicare.gov/hospitalcompare/cancer-measures.html*. We note that this measure is updated on an annual basis, and that new *Hospital Compare* data is published four times each year: April, July, October, and December. As such, we anticipate an update of EBRT measure data to be available in December of 2018.

d. Summary of Proposed Public Display Requirements for the FY 2021 Program Year

Our proposed public display requirements for the FY 2021 program year are shown in the following table:

PROPOSED PUBLIC DISPLAY REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR

Summary of newly proposed public display requirements

Measures	Public reporting
• HCAHPS (NQF #0166)	2016 and subsequent years.
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• 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).	*Deferred Until Calendar Year 2019.
• 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).	

[359] Centers for Disease Control and Prevention. ''Paving Path Forward: 2015 Rebase line.'' Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html*.

[360] Rebase line Timeline FAQ Document. Available at: *https://www.cdc.gov/nhsn/pdfs/rebaseline/faq-timeline-rebaseline.pdf*.

PROPOSED PUBLIC DISPLAY REQUIREMENTS FOR THE FY 2021 PROGRAM YEAR—Continued

Summary of newly proposed public display requirements	
Measures	Public reporting
• External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822)	2017 and subsequent years.

* Newly proposed in this FY 2019 IPPS/LTCH PPS proposed rule.

9. Form, Manner, and Timing of Data Submission

a. Background

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet website at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228*.

b. Proposed Reporting Requirements for the Newly Proposed 30-Day Unplanned Readmissions for Cancer Patients Measure

As further described in section VIII.B.4.b. of the preamble of this proposed rule, we are proposing the adoption of a new measure beginning with the FY 2021 program year, the 30-Day Unplanned Readmissions for Cancer Patients measure. This is a claims-based measure, therefore, there will be no separate data submission requirements for PCHs related to this measure as CMS will calculate measure rates from PCH claims data. We are proposing that the data collection period would be from July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. Therefore, for the FY 2021 program year, we would collect data from October 1, 2018 through September 30, 2019.

We are inviting public comment on this proposal.

10. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

In our experience with other quality reporting and performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to increase their burden unduly during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program year and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers) [361] with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. The PCH may request a reporting extension or a complete exception from the requirement to submit quality data for one or more quarters. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38424 through 38425), we finalized modifications to the extraordinary circumstances exceptions (ECE) policy to extend the deadline for a PCH to submit a request for an extension or exception from 30 days following the date that the extraordinary circumstance occurred to 90 days following the date that the extraordinary circumstance occurred and to allow CMS to grant an exception or extension due to CMS data system issues which affect data submission. In addition, to ensure transparency and understanding of our process, we have clarified that we will strive to provide our response to an ECE request within 90 days of receipt.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background

The 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 reduces by two 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 detailed 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), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426).

Although we have historically used the preamble to the IPPS/LTCH PPS proposed and final rules each year to remind stakeholders of all previously finalized program requirements, we have concluded that repeating the same discussion each year is not necessary for every requirement, especially if we have codified it in our regulations. Accordingly, the following discussion is limited as much as possible to a discussion of our proposals for future years of the LTCH QRP, and represents the approach we intend to use in our rulemakings for this program going forward.

2. General Considerations Used for the Selection of Measures for the LTCH QRP

a. Background

For a detailed discussion of the considerations we historically used for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

b. Accounting for Social Risk Factors in the LTCH QRP

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428 through 38429), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[362] Among our core objectives, we aim to improve health outcomes, attain health

[361] ECEs were originally referred to as ''waivers.'' This term was changed to ''exceptions'' in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

[362] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[363] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38404), ASPE's report to Congress, which was required by the IMPACT Act, found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38428), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[364] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[365] allowing further examination of social risk factors in outcome measures.

In the FY 2018/CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS: To explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

[363] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[364] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[365] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

3. Proposed New Measure Removal Factor for Previously Adopted LTCH QRP Measures

As a part of our Meaningful Measures Initiative, discussed in section I.A.2. of the preamble of this proposed rule, we strive to put patients first, ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using data-driven information that is increasingly aligned with a parsimonious set of meaningful quality measures. We began reviewing the LTCH QRP's measures in accordance with the Meaningful Measures Initiative, and we are working to identify how to move the LTCH QRP forward in the least burdensome manner possible, while continuing to incentivize improvement in the quality of care provided to patients.

Specifically, we believe the goals of the LTCH QRP and the measures used in the program cover most of the Meaningful Measures Initiative priorities, including making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable.

We also evaluated the appropriateness and completeness of the LTCH QRP's current measure removal factors. We have previously finalized that we would use notice and comment rulemaking to remove measures from the LTCH QRP based on the following factors (77 FR 53614 through 53615): [366]

- Factor 1. Measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.
- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.
- Factor 7. Collection or public reporting of a measure leads to negative

[366] We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615) for more information on the factors we consider for removing measures.

unintended consequences other than patient harm.

We continue to believe that these measure removal factors are appropriate for use in the LTCH QRP. However, even if one or more of the measure removal factors applies, we may nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could, in turn, result in poor quality, or in the event that a given measure is statutorily required. We note further that, consistent with other quality reporting programs, we apply these factors on a case-by-case basis.

We are proposing to adopt an additional factor to consider when evaluating potential measures for removal from the LTCH QRP measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in section I.A.2. of the preamble of this proposed rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the LTCH QRP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) The provider and clinician information collection burden and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the cost to CMS associated with the program oversight of the measure including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable).

For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools we need to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the LTCH QRP, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the LTCH QRP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the LTCH QRP may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We also are proposing to codify both the removal factors we previously finalized for the LTCH QRP, as well as the new the measure removal factor that we are proposing to adopt in this rule, at § 412.560(b)(3) of our regulations.

We are inviting public comment on these proposals.

4. Quality Measures Currently Adopted for the FY 2020 LTCH QRP

The LTCH QRP currently has 19 measures for the FY 2020 program year, which are outlined in the following table:

QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2020 LTCH QRP

Short name	Measure name and data source
LTCH CARE Data Set	
Pressure Ulcer	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).*
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Patient Influenza Vaccine	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).
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.

QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2020 LTCH QRP—Continued

Short name	Measure name and data source
Ventilator Liberation	Ventilator Liberation Rate.
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).
MRSA	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).
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).
VAE	National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.
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).

* The measure will be replaced with the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective July 1, 2018.

5. Proposed Removal of Three LTCH QRP Measures

We are proposing to remove three measures from the LTCH QRP measure set. Beginning with the FY 2020 LTCH QRP, we are proposing to remove two measures: (1) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); and (2) National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure. We are proposing to remove one measure beginning with the FY 2021 LTCH QRP: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680). We discuss these proposals below.

a. Proposed Removal of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

We are proposing to remove the measure, National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), from the LTCH QRP beginning with the FY 2020 LTCH QRP.

As discussed in section VIII.C.3. of the preamble of this proposed rule, one of the main goals of our Meaningful Measures Initiative is to apply a parsimonious set of the most meaningful measures available to track patient outcomes and impact. We currently collect data on two measures of healthcare-associated bacteremia infections in the LTCH QRP: (1) NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139); and (2) NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).

In our review of these measures used in the LTCH QRP, we believe that it is appropriate to remove the NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) based on: (1) Factor 6, a measure that is more strongly associated with desired patient outcomes for the particular topic is available; and (2) proposed Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We believe that the NHSN CLABSI Outcome Measure (NQF #0139) is more strongly associated with the desired patient outcome for bloodstream infections than the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716). Bloodstream infections are serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality. The NHSN CLABSI Outcome Measure (NQF #0139) assesses the results of the quality of care provided to patients, and it is risk-adjusted to compare the infection rate for a particular location or locations in a hospital with an expected infection rate for those locations (which is calculated using national NHSN data for those locations in a predictive model). The NHSN CLABSI Outcome Measure (NQF #0139) is more strongly associated with the desired patient outcome of better results in the quality of care provided to patients because it covers a wide range of blood-stream infections, while the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) only covers MRSA observed hospital-onset unique blood source MRSA laboratory-identified events. The NHSN CLABSI Outcome Measure (NQF #0139) also captures the MRSA blood-stream events, creating potential duplicative collection and reporting.

We also believe that the costs associated with the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) outweigh the benefit of its continued use in the LTCH QRP. The NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) was adopted to assess MRSA infections caused by a strain of MRSA bacteremia that has become resistant to antibiotics commonly used to treat MRSA infections. The NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) and NHSN CLABSI Outcome Measure (NQF #0139) capture the same

type of MRSA infection. This overlap results in the data submission on two measures that cover the same quality issue. We believe that this results in redundant efforts on the part of LTCHs that are costly and burdensome. In addition, the maintenance of these two measures in the LTCH QRP is costly for CMS. Lastly, we believe that the removal of the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716) would benefit the public by eliminating the potential confusion of seeing two different measure rates on LTCH Compare that capture MRSA bacteremia.

If finalized, LTCHs would continue to report MRSA bacteremia events associated with central line use as part of the NHSN CLABSI Outcome Measure (NQF #0139), and LTCHs would additionally report as part of that measure other acquired central line-associated bloodstream infections. As a result, duplication of data submission of the same MRSA bacteremia event for these two measures would be eliminated and only a single bacteremia outcome measure would be publicly reported on *LTCH Compare.*

Therefore, we are proposing to remove the NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) from the LTCH QRP beginning with the FY 2020 LTCH QRP under: (1) Factor 6, a measure that is more strongly associated with desired patient outcomes for the particular topic is available; and (2) proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

If finalized as proposed, LTCHs would no longer be required to submit data on this measure for the purposes of the LTCH QRP beginning with October 1, 2018 admissions and discharges.

We are inviting public comment on this proposal.

b. Proposed Removal of the National Healthcare Safety Network (NHSN) Ventilator-Associated-Event (VAE) Outcome Measure

We are proposing to remove the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP beginning with the FY 2020 LTCH QRP based on Factor 6, a measure that is more strongly associated with desired patient outcomes for the particular topic is available.

We finalized the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305) to assess whether LTCHs monitor ventilator use and identify improvements in preventing complications associated with mechanical ventilation. We have also adopted for the LTCH QRP three other assessment-based quality measures on the topic of ventilator support: (1) Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) (79 FR 50298 through 50301); (2) Compliance with Spontaneous Breathing Trials (SBT) by Day 2 of the LTCH Stay (82 FR 38439 through 38443); and (3) Ventilator Liberation Rate (82 FR 38443 through 38446).

We believe that these three other assessment-based quality measures are more strongly associated with desired patient outcomes than the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure that we are proposing to remove. The three assessment-based measures assess activities that reduce the potential for serious complications and other adverse events as a result of mechanical ventilation. Specifically, the Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) focuses on improvement in functional mobility for patients requiring mechanical ventilation. The Compliance with SBT by Day 2 of the LTCH Stay measure focuses on successfully liberating patients from mechanical ventilation as soon as possible, which reduces the risk associated with events as a result of prolonged ventilator support. The Ventilator Liberation Rate measure assesses whether the patient was fully liberated from mechanical ventilation at discharge. Together, these three ventilator-related assessment-based quality measures assess positive outcomes and track patient goals of avoiding adverse outcomes associated with mechanical ventilation and successful ventilator weaning.

The inclusion in the LTCH QRP measure set of these three ventilator-related assessment-based measures, which focus on quality of care through promotion of positive outcomes, have reduced poor outcomes associated with the complications of ventilator care, which is the same focus of the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure (for example, worsening oxygenation, infection or inflammation, ventilator-associated pneumonia, or even death). As a result, we do not believe that it is necessary to retain all four of these measures in the LTCH QRP. By retaining the three ventilator-related assessment-based measures but removing the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure, we believe that we can focus our mechanical ventilation topic measures on measures that promote positive outcomes while indirectly promoting a reduction in ventilator support complications.

For these reasons, we are proposing to remove the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP beginning with the FY 2020 LTCH QRP under Factor 6, the measure that is more strongly associated with desired patient outcomes for the particular topic is available.

If finalized as proposed, LTCHs would no longer be required to submit data on this measure for the purposes of the LTCH QRP beginning with October 1, 2018 admissions and discharges.

c. Proposed Removal of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) Measure

We are proposing to remove the process measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 LTCH QRP under proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

This process measure reports the percentage of stays in which a patient was assessed and appropriately given the influenza vaccine for the most recent influenza vaccination season and was adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627) to assess vaccination rates among older adults with the goal of reducing the incidence of influenza in this population. Specifically, adoption of the measure in the LTCH QRP was intended to act as a safeguard for patients who did not receive vaccinations prior to admission to an LTCH, since many patients receiving care in the LTCH setting are older adults, those 65 years and older, considered to be the target population for the influenza vaccination.

In our evaluation of the LTCH QRP measure set, our analysis of this particular measure revealed that for the 2016–2017 influenza season, nearly every patient was assessed by the LTCH upon admission and that less than 0.04 percent of patients were not assessed for

the vaccination. Of those assessed, the data show that most patients who could receive the vaccine had already received the vaccine outside of the LTCH facility, prior to admission.

In addition, we have heard from stakeholders that the data collection associated with this measure is administratively costly and burdensome for LTCHs, and that the process of assessing whether vaccination is needed is often a duplicative process for patients who were already screened during their proximal stay at an acute care facility. We believe that removing this measure would reduce provider costs and burden by eliminating duplicative patient assessments across healthcare settings, minimizing data collection and reporting, and avoiding potentially confusing public reporting of other influenza-related quality measures, such as the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure.

We recognize that influenza is a major public health issue. However, based on our analysis of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure, including data showing that most LTCH patients are vaccinated before they are admitted to the LTCH, we believe that LTCH patients will continue to be assessed and immunized when appropriate in the absence of this measure. As a result, removal of this measure would alleviate the operational costs and burden that LTCHs currently incur with respect to collecting the data necessary to report this measure.

Therefore, we are proposing to remove this measure from the LTCH QRP beginning with the FY 2021 LTCH QRP under proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

If finalized as proposed, LTCHs would no longer be required to report the data elements necessary to calculate this measure beginning with October 1, 2018 [367] admissions and discharges. We plan to remove the data elements from the LTCH CARE Data Set as soon as feasible. Beginning with October 1, 2018 admissions and discharges, LTCHs should enter a dash (–) for O0250A, O0250B, and O0250C until the next LTCH CARE Data Set is released.

We are inviting public comment on this proposal.

6. IMPACT Act Implementation Update

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38449), we stated that we intended to specify two measures that would satisfy the domain of accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than October 1, 2018, and intended to propose to adopt them for the FY 2021 LTCH QRP with data collection beginning on or about April 1, 2019.

As a result of the input provided during a public comment period initiated by our contractor between November 10, 2016 and December 11, 2016, input provided by a technical expert panel (TEP) convened by our contractor, and pilot measure testing conducted in 2017, we are engaging in continued development work on these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. Further, we expect to reconvene a TEP for these measures in mid-2018. We now intend to specify the measures under section 1899B(c)(1)(E) of the Act no later than October 1, 2019 and intend to propose to adopt the measures for the FY 2022 LTCH QRP, with data collection beginning with April 1, 2020 admissions and discharges. For more information on the pilot testing, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html*.

7. Form, Manner, and Timing of Data Submission Under the LTCH QRP

Under our current policy, LTCHs report data on LTCH QRP assessment-based measures and standardized patient assessment data by reporting the designated data elements for each applicable patient on the LTCH CARE Data Set patient assessment instrument and then submitting the completed instruments to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system. Data on LTCH QRP measures that are also collected by the Centers for Disease Control and Prevention (CDC) for other purposes are reported by LTCHs to the CDC through the NHSN, and the CDC then transmits the relevant data to CMS. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38454 through 38456) for the data collection and submission timeframes that we finalized for the LTCH QRP.

We are seeking input on whether we should move the implementation date of any new version of the LTCH CARE Data Set from the usual release date of April to October in the future.

We are inviting public comment on this topic.

8. Proposed Changes to the LTCH QRP Reconsideration Requirements

Section 412.560(d)(1) of our regulations states that CMS will send an LTCH written notification of a decision of noncompliance with the measures data and standardized patient assessment data reporting requirements for a particular fiscal year. It also states that CMS will use the QIES ASAP system to provide notification of noncompliance to the LTCH.

We are proposing to revise § 412.560(d)(1) to expand the methods by which we would notify an LTCH of noncompliance with the LTCH QRP requirements for a program year. Revised § 412.560(d)(1) would state that we would notify LTCHs of noncompliance with the LTCH QRP requirements via a letter sent through at least one of the following notification methods: The QIES ASAP system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). We believe this change will address the feedback from providers requesting additional methods for notification.

We are also proposing to revise § 412.560(d)(3) to clarify that we will notify LTCHs, in writing, of our final decision regarding any reconsideration request using the same notification process.

We are inviting public comments on these proposals.

D. Proposed Changes to the Medicare and Medicaid EHR Incentive Programs (Now Referred to as the Medicare and Medicaid Promoting Interoperability Programs)

1. Background

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 are available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of

[367] The October 1, 2018 date is proposed as the date in which LTCHs would no longer be required to report the data elements necessary to calculate this measure because the influenza vaccination season for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure begins October 1, 2018 and ends March 31, 2019, and includes all patients who were in an LTCH for one or more days during the influenza vaccination season.

the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs or eCQMs) using CEHRT. Incentive payments are available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that meaningfully use CEHRT.

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 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 certified EHR technology, 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.

2. Renaming the EHR Incentive Program

The Medicare and Medicaid EHR Incentive Programs has historically been broken into three stages primarily focused on data capture and sharing, advanced clinical processes, and improved outcomes. In this proposed rule, we are proposing scoring and measurement policies to move beyond the three stages of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To better reflect this focus, we are renaming the Medicare and Medicaid EHR Incentive Programs to the Promoting Interoperability (PI) Programs, and the new name will apply for Medicare fee-for-service, Medicare Advantage, and Medicaid. We believe this change will help highlight the enhanced goals of the program and better contextualize the program changes discussed in the following sections. We also note that the former name, Medicare and Medicaid EHR Incentive Programs, does not adequately reflect the current status of the programs, as the incentive payments under Medicare generally have ended (with the exception of subsection (d) Puerto Rico hospitals as discussed in section VIII.D.10. of the preamble of this proposed rule) and will end under Medicaid in 2021.

3. Certification Requirements Beginning in 2019

In the October 16, 2015 final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule'' (80 FR 62761 through 62955) (hereafter referred to as the ''2015 EHR Incentive Programs final rule''), we adopted a final policy regarding which Edition of CEHRT must be used by EPs, eligible hospitals, and CAHs for the EHR Incentive Programs, which was reflected in the definition of CEHRT under § 495.4 (80 FR 62871 through 62875). Under this policy, starting with 2018, all EPs, eligible hospitals, and CAHs would be required to use technology certified to the 2015 Edition to demonstrate meaningful use for an EHR reporting period in 2018 and subsequent years (80 FR 62873 through 62875). We subsequently finalized in the FY 2018 IPPS/LTCH PPS final rule certain changes to the policy that would allow for CEHRT flexibility in 2018, allowing health care providers in the Medicare and Medicaid EHR Incentive Programs to use either the 2014 or 2015 Edition of CEHRT, or a combination of both Editions, in 2018 (82 FR 38490 through 38493). This flexibility would give additional time to health care providers who may need to update, implement, and optimize the technology certified to the 2015 Edition and was only allowed for 2018. Beginning with the EHR reporting period in CY 2019, the 2015 Edition of CEHRT is required pursuant to the definition of CEHRT under § 495.4. We are not proposing to change this policy, and, as discussed below, we continue to believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. In reviewing the state of health information technology, it is clear the 2014 Edition certification criteria are out of date and insufficient for provider needs in the evolving health IT industry. It would be beneficial to health IT developers and health care providers to move to more up-to-date standards and functions that better support interoperable exchange of health information and improve clinical workflows.

The 2014 Edition CEHRT, which was first issued in regulations in 2012, now includes standards that are significantly out of date, which can impose artificial limits on interoperability and the access, exchange, and use of health information. Moving from certifying to the 2014 Edition to certifying to the 2015 Edition would also eliminate the inconsistencies that are inherent with maintaining and implementing two separate certification programs. In the last calendar year, the number of new and unique 2014 Edition products have been declining, showing that the market acknowledges the shift toward newer and more effective technologies. The vast majority of 2014 Edition certifications are for inherited certified status. The resulting legacy systems, while certified to the 2014 Edition, are not the most up-to-date and detract from health information technology's (IT's) goal of increasing interoperability and increasing the access, exchange, and use of health data.

Prolonging backwards compatibility of newer products to legacy systems causes market fragmentation. Health IT stakeholders noted the impact of system fragmentation on the cost to develop and maintain health IT connectivity to support data exchange, develop products to support specialty clinical care, and integrate software supporting administrative and clinical processes. As previously stated, a large proportion of the sector is ready to solely use the 2015 Edition; maintaining a requirement to keep both certification editions contributes to market fragmentation, which heightens implementation costs for health IT developers, hospitals, and health care providers. Developers and consumers that are required to maintain two different certification editions, spend large amounts of money on the recertification of older products, which diverts resources from the development, maintenance, and implementation of more advanced technologies, including the 2015 Edition of CEHRT.

In addition to the monetary savings of the 2015 Edition, there will also be an impactful reduction of burden across many settings. Eligible hospitals and CAHs will see a reduction in burden through relief from being required to certify to a legacy system, and can use the 2015 Edition to better streamline workflows and utilize more comprehensive functions to meet patient safety goals and improve care coordination across the continuum. Maintaining only one edition of certification requirements would also reduce the burden for health IT developers as well as ONC-authorized testing laboratories and certification bodies because they would no longer have to support two, increasingly distant sets of requirements.

One of the major improvements in the 2015 Edition is the application programming interface (API) functionality. The API functionality supports health care providers and patient electronic access to health information. These functions allow for

patient data to move between systems and assist patients with making key decisions about their health care. The functions also contribute to quality improvement and greater interoperability between systems. The API has the ability to complement a specific provider branded patient portal or could also potentially make one unnecessary if patients are able to use software applications designed to interact with an API that could support their ability to view, download, and transmit their health information to a third party (80 FR 62842). Furthermore, the API allows for third-party application usage with more flexibility and smoother workflow from various systems than what is often found in many current patient portals.

The 2015 Edition also includes certification criterion specifying a core set of data that health care providers have noted are critical to interoperable exchange and can be exchanged across a wide variety of other settings and use cases, known as the Common Clinical Data Set (C–CDS) (80 FR 62603). The US Core Data for Interoperability (USCDI) builds off the Common Clinical Data Set definition adopted for the 2015 Edition of certified health IT and referenced in the EHR Incentive Program, for instance as the data which must be included in a summary care record. The USCDI aims to support the goals set forth in the 21st Century Cures Act by specifying a common set of data classes that are required for interoperable exchange and identifying a predictable, transparent, and collaborative process for achieving those goals. The USCDI is referenced by the Draft Trusted Exchange Framework,[368] which is intended to enable HINs and Qualified HINs to securely exchange electronic health information in support of a range permitted purposes, including treatment, payment, operations, individual access, public health, and benefits determination.

We also note that the Provide Patient Access measure's technical requirements are updated in the 2015 Edition and support health care providers' interest in providing patients with access to their data in a manner that is helpful to the patient and aligns with the API requirement in the Promoting Interoperability Program. This includes a new function that supports patient access to their health information through email transmission to any third party the patient chooses and through a second encrypted method of transmission. As discussed above the increased interoperability in this requirement provides patients more control of their health data to inform the decisions that they make regarding their health.

The 2015 Edition also includes a revised requirement that products must be able to export data from one patient, a set of patients, or a subset of patients, which is responsive to health care provider feedback that their data is unable to carry over from a previous EHR. The 2014 Edition did not include a requirement that the vendor allow the health care provider to export the data themselves. In the 2015 Edition, the health care provider has the autonomy to export data themselves without intervention by their vendor, resulting in increased interoperability and data exchange in the 2015 Edition.

In efforts to track certification readiness for the 2015 Edition, the Office of the National Coordinator for Health Information Technology (ONC) considers the number of health care providers likely to be served by the developers seeking certification under the ONC Health IT Certification Program in real time as the testing and certification process progresses. The ONC considers trends within the industry when projecting for 2015 Edition readiness. This is based on the major developers who have a major share of the market. In working with ONC we are able to identify the percent of eligible clinicians, eligible hospitals and CAHs that have a 2015 Edition available to them based on vendor readiness and information. As of the beginning of the first quarter of CY 2018, ONC confirmed that at least 66 percent of eligible clinicians and 90 percent of eligible hospitals and CAHs have 2015 Edition available based on previous EHR Incentive Programs attestation data. Based on the data, and as compared to the transition from 2011 Edition to 2014 Edition, it appears that the transition from the 2014 Edition to the 2015 Edition is on schedule for the EHR reporting period in CY 2019.

We note that this information is current as of the beginning of CY 2018, and based on historical data, we expect readiness to continue to improve as developers and health care providers prepare for program participation using the 2015 Edition in CY 2019.

We continue to recognize there is a burden associated with development and deployment of new technology, but we believe requiring use of the most recent version of CEHRT is important in ensuring health care providers use technology that has improved interoperability features and up-to-date standards to collect relevant patient health information. The 2015 Edition includes key updates to functions and standards that support improved interoperability and clinical effectiveness through the use of health IT.

4. Proposed Revisions to the EHR Reporting Period in 2019 and 2020

We continue to receive feedback from EPs, eligible hospitals, hospital associations, and other clinical associations indicating that additional time will be necessary for testing and implementation of the new API functionality requirement for Stage 3. These organizations cite both an inability to meet the required timeframe for implementation of Stage 3 and the complexity of the new functionality and associated requirements for the Patient Electronic Access to Health Information (80 FR 62841 through 62846) and Coordination of Care Through Patient Engagement (80 FR 62846 through 62852) objectives.

API functionality supports health care providers and patient electronic access to health information, which is key to improving the free flow of health information, interoperability, quality improvement, and patient engagement. This functionality is included as part of the 2015 Edition base EHR definition (and thus must be part of CEHRT) (80 FR 62675 through 62676), and we believe that the access APIs permit may prove valuable in many ways. For example, APIs may be enabled by a health care provider or organization to facilitate their own use of third party applications within their CEHRT, such as for quality improvement. An API could also be enabled by a health care provider to give patients access to their health information through a third-party application with more flexibility than is often found in many current patient portals. From the health care provider perspective, an API could complement a specific provider branded patient portal or could also potentially make one unnecessary if patients are able to use software applications designed to interact with an API that could support their ability to view, download, and transmit their health information to a third party (80 FR 62842). We want to ensure that health care providers have the opportunity to thoroughly test their systems and make adjustments in order to successfully attest for the EHR reporting periods in CYs 2019 and 2020. In addition, we believe that health care providers may need extra time to fully implement and test workflows with the 2015 Edition of CEHRT, which is required beginning in CY 2019, as well as the current proposal to require use of

[368] *https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf.*

an API to incorporate patient data in the Provide Patients Electronic Access to Their Health Information measure discussed in section VIII.D.6.d.(1) of the preamble of this proposed rule.

We also are proposing in section VIII.D.5. of the preamble of this proposed rule an updated scoring methodology for eligible hospitals and CAHs that would begin in 2019, as well as two new opioid measures and one new health information exchange measure that we believe eligible hospitals and CAHs will want to report on as soon as those measures are available in their CEHRT. We want to provide flexibility to health care providers as they are becoming familiar with the new scoring methodology and measures that we are proposing, as well as adequate development time for EHR developers and vendors to test and incorporate the new scoring system and measures for deployment and implementation. Therefore, we are proposing changes to the EHR reporting periods in 2019 and 2020 and believe the changes would result in a reduction in burden on health care providers and EHR developers and vendors. We are proposing these changes for 2019 and 2020 as we believe it may take more than one year for eligible hospitals and CAHs to adjust to the new scoring methodology proposed in section VIII.D.5. of the preamble of this proposed rule.

For the reasons discussed earlier, we are proposing the EHR reporting periods in 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency would be a minimum of any continuous 90-day period within each of the calendar years 2019 and 2020. This would mean that EPs that attest to a State for the State's Medicaid Promoting Interoperability Program and eligible hospitals and CAHs attesting to CMS or the State's Medicaid Promoting Interoperability Program would attest to meaningful use of CEHRT for an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2019 through December 31, 2019 and from January 1, 2020 through December 31, 2020, respectively.

The applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2019 and 2020, as well as the deadlines for attestation and other related program requirements, would remain the same as established in prior rulemaking. We are proposing corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

We are inviting public comment on our proposal.

5. Proposed Scoring Methodology for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

a. Background

Section 1886(n)(3) of the Act establishes criteria for an eligible hospital or CAH to be considered a meaningful EHR user for the Medicare Promoting Interoperability Program. Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), section 1886(n)(3)(A) of the Act required the Secretary to seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use. This resulted in three separate stages of meaningful use requirements, each with increasing stringency of reporting requirements. The July 28, 2010 final rule titled, ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' (75 FR 44313 through 44588), hereafter referred to as the ''Stage 1 final rule,'' established the foundation for the Medicare and Medicaid EHR Incentive Programs by outlining the applicable meaningful use criteria and finalizing core and menu objectives for EPs, eligible hospitals, and CAHs, including establishing requirements for the electronic capture of clinical data, and providing patients with electronic copies of their health information (75 FR 44313 through 44588). In the September 4, 2012 final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2'' (77 FR 53967 through 54162), hereafter referred to as the ''Stage 2 final rule,'' we focused on the next goal: The exchange of essential health data among health care providers and patients to improve care coordination. Lastly, the 2015 EHR Incentive Programs final rule established a single set of objectives and measures that increased stringency by requiring patient action measures and increasing measure thresholds, which contributed to the goal of widespread adoption and advanced use of electronic health record technology for Stage 3 in 2017 and subsequent years (80 FR 62762 through 62915). The provision in section 1886(n)(3)(A) of the Act requiring more stringent measures of meaningful use over time was subsequently removed by section 50413 of the Bipartisan Budget Act of 2018.

As we considered the future direction of EHR reporting for the Promoting Interoperability Program, we considered how to increase the focus of EHR reporting on interoperability and sharing data with patients. We also considered the history of the program stages, as well as the increased flexibility provided by the Bipartisan Budget Act of 2018. In light of these considerations, we are proposing a new scoring methodology that reduces burden and provides greater flexibility to hospitals while focusing on increased interoperability and patient access.

We have received feedback from hospitals and hospital associations that the current meaningful use requirements are not always meaningful to them and detract from their ability to provide care to their patients. They have further suggested, through inquiries and listening sessions, that the requirement to meet all of the measures has been administratively burdensome, particularly those that require patient action. These stakeholders believe there is a critical need for interoperability and have expressed a desire to use CEHRT to further patient outcomes, but believe the current program structure constrains their ability to implement more interoperable practices and deliver quality care. An example of this feedback came from hospitals and hospital associations regarding the View, Download or Transmit (VDT) measure which requires at least one unique patient (or their authorized representative) discharged from the eligible hospital or CAH to access their health information through the use of an API, view, download or transmit their health information to a third party or a combination of both. These hospitals and hospital associations have indicated that, although they can encourage their patients to access their data electronically and through this type of platform, it is beyond their control to require such action. They further indicated that they are unable to require patients to perform actions that patients do not feel accustomed to, and that certain patient populations are not comfortable with such actions.

In addition, through our listening sessions we found that certain rural hospitals find it more challenging to meet all of the measure thresholds and requirements due to financial limitations. Many of these rural hospitals expressed an interest in fully participating in the Medicare EHR Incentive Program, but stated they are only able to meet a subset of the objectives and measures. They stated that a new scoring and reporting structure that would allow them to focus on their patient population would help them successfully participate in the program.

Based on this feedback and the recent statutory changes, we are proposing a new performance-based scoring methodology with fewer measures, and moving away from the threshold-based methodology that we currently use. We believe this change would provide a more flexible, less burdensome structure, allowing eligible hospitals and CAHs to put their focus back on patients. The introduction of a performance-based scoring methodology would continue to encourage hospitals to push themselves on measures that we continue to hear are most applicable to how they deliver care to patients, instead of increasing thresholds on measures that may not be as applicable to an individual hospital. Our goal is to provide increased flexibility to eligible hospitals and CAHs without compromising the integrity of the Medicare Promoting Interoperability Program and enable them to focus more on patient care and health data exchange through interoperability.

We are proposing the performance-based scoring methodology would apply to eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019. This would include ''Medicare-only'' eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use) as well as ''dual-eligible'' eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use, and are also eligible to earn a Medicaid incentive payment for meaningful use).

We are not proposing to apply the performance-based scoring methodology to ''Medicaid-only'' eligible hospitals (those that are only eligible to earn a Medicaid incentive payment for meaningful use of CEHRT, and are not eligible for an incentive payment under Medicare for meaningful use and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use) that submit an attestation to their State Medicaid agency for the Medicaid Promoting Interoperability Program. Instead, as discussed in section VIII.D.7. of the preamble of this proposed rule, we are proposing to give States the option to adopt the performance-based scoring methodology along with the measure proposals discussed in section VIII.D.6. of the preamble of this proposed rule for their Medicaid Promoting Interoperability Programs through their State Medicaid HIT Plans.

To accomplish our goal of a performance-based program that reduces burden while promoting interoperability, and taking into account the feedback from our stakeholders, we outline a proposal using a performance-based scoring methodology in the following sections of this proposed rule. We believe the proposal promotes interoperability, helps to maintain a focus on patients, reduces burden and provides greater flexibility. The proposal takes an approach that weighs each measure based on performance, and allows eligible hospitals and CAHs to emphasize measures that are most applicable to their care delivery methods, while putting less emphasis on those measures that may be less applicable.

If we do not finalize a new scoring methodology, we would maintain the current Stage 3 methodology with the same objectives, measures and requirements, but we would include the two new opioid measures proposed in section VIII.D.6.b. of the preamble of this proposed rule, if finalized. The current structure of the Stage 3 objectives and measures under § 495.24(c) for eligible hospitals and CAHs attesting to CMS requires them to report on six objectives that include 16 measures. This structure requires the eligible hospital or CAH to report on all measures and meet the thresholds for most of the measures or claim an exclusion as part of demonstrating meaningful use to avoid the payment adjustment, or to earn an incentive in the case of subsection (d) Puerto Rico hospitals. A general summary overview of the current objectives, measures, and reporting requirements is included in the table below.

EXISTING STAGE 3 OBJECTIVES, MEASURES AND REPORTING REQUIREMENTS FOR THE MEDICARE EHR INCENTIVE PROGRAM FOR ELIGIBLE HOSPITALS AND CAHS

Objective	Measure (stage 3 threshold)	Reporting requirement
Protect Patient Health Information	Security Risk Analysis (Yes/No)	Report.
Electronic Prescribing	e-Prescribing (>25%)	Report and meet threshold.
Patient Electronic Access to Health Information.	Provide Patient Access (>50%)	Report and meet thresholds.
	Patient Specific Education (>10%)	
Coordination of Care Through Patient Engagement.	View, Download or Transmit (at least one patient)	Report all, but only meet the threshold for two.
	Secure Messaging (>5%)	
	Patient Generated Health Data (>5%)	
Health Information Exchange	Send a Summary of Care (>10%)	Report all, but only meet the threshold for two.
	Request/Accept Summary of Care (>10%)	
	Clinical Information Reconciliation (>50%)	
Public Health and Clinical Data Registry Reporting.	Immunization Registry Reporting	Report Yes/No to Three Registries.
	Syndromic Surveillance Reporting	
	Electronic Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	

b. Proposed Performance-Based Scoring Methodology

We are proposing a new scoring methodology to include a combination of new measures, as well as the existing Stage 3 measures of the EHR Incentive Program, broken into a smaller set of four objectives and scored based on performance and participation. We believe this is a significant overhaul of the existing program requirements which include six objectives, scored on a pass/fail basis. The smaller set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. We are

proposing these objectives to promote specific HHS priorities. We include the e-Prescribing and Health Information Exchange objectives in part to capture what we believe are core goals for the 2015 Edition in line with section 1886(n)(3)(A) of the Act. These core goals promote interoperability between health care providers and health IT systems to support safer, more coordinated care. The Provider to Patient Exchange objective promotes patient awareness and involvement in their health care through the use of APIs, and ensures patients have access to their medical data. Finally, the Public Health and Clinical Data Exchange objective supports the ongoing systematic collection, analysis, and interpretation of data that may be used in the prevention and controlling of disease through the estimation of health status and behavior. The integration of health IT systems into the national network of health data tracking and promotion improves the efficiency, timeliness, and effectiveness of public health surveillance. We believe it is important to keep these core goals, primarily because these objectives promote interoperability between health care providers and health IT systems to support safer, more coordinated care while ensuring patients have access to their medical data.

Under the proposed scoring methodology, eligible hospitals and CAHs would be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure would be scored based on the eligible hospital or CAH's performance for that measure, except for the Public Health and Clinical Data Exchange objective, which requires a yes/no attestation. Each measure would contribute to the eligible hospital or CAH's total Promoting Interoperability (PI) score. The scores for each of the individual measures would be added together to calculate the total Promoting Interoperability score of up to 100 possible points for each eligible hospital or CAH. A total score of 50 points or more would satisfy the requirement to report on the objectives and measures of meaningful use under § 495.24, which is one of the requirements for an eligible hospital or CAH to be considered a meaningful EHR user under § 495.4 and thus earn an incentive payment and/or avoid a Medicare payment reduction. Eligible hospitals and CAHs scoring below 50 points would not be considered meaningful EHR users.

While this approach maintains some of the same requirements of the EHR Incentive Program, we note that we are proposing to reduce the overall number of required measures from 16 to 6. We also note that the measures we are proposing to include contribute to the goal of increased interoperability and patient access, and no longer require the burdensome predefined thresholds of the EHR Incentive Program, and thus allow new flexibility for eligible hospitals and CAHs in how they are scored. We believe this proposal allows eligible hospitals and CAHs to achieve high performance in one area where they excel, in order to offset performance in an area where they may need additional improvement. In this manner we believe eligible hospitals and CAHs could still be considered meaningful EHR users while continuing to monitor their progress on each of the measures. This approach also helps further promote interoperability by requiring all measures and thus all forms of interoperability across the three objectives.

We also considered an alternative approach in which scoring would occur at the objective level, instead of the individual measure level, and eligible hospitals or CAHs would be required to report on only one measure from each objective to earn a score for that objective. Under this scoring methodology, instead of six required measures, the eligible hospital or CAH's total Promoting Interoperability score would be based on only four measures, one measure from each objective. Each objective would be weighted similarly to how the objectives are weighted in our proposed methodology, and bonus points would be awarded for reporting any additional measures beyond the required four. We are seeking public comment on this alternative approach, and whether additional flexibilities should be considered, such as allowing eligible hospitals and CAHs to select which measures to report on within an objective and how those objectives should be weighted, as well as whether additional scoring approaches or methodologies should be considered.

In our proposed scoring methodology, the e-Prescribing objective would contain three measures each weighted differently to reflect their potential availability and applicability to the hospital community. In addition to the existing e-Prescribing measure, we are proposing to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. For more information about these two proposed measures, we refer readers to section VIII.D.6.b. of the preamble of this proposed rule. The e-Prescribing measure would be required for reporting and weighted at 10 points because we believe it would be applicable to most eligible hospitals and CAHs. In the event that an eligible hospital or CAH meets the criteria and claims the exclusion for the e-Prescribing measure in 2019, the 10 points available for that measure would be redistributed equally among the measures under the Health Information Exchange objective:

- Support Electronic Referral Loops By Sending Health Information Measure (25 points)
- Support Electronic Referral Loops By Receiving and Incorporating Health Information (25 points)

We are seeking public comment on whether this redistribution is appropriate for 2019, or whether the points should be distributed differently.

The Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement measures would be optional for EHR reporting periods in 2019. These new measures may not be available to all eligible hospitals and CAHs for an EHR reporting period in 2019 as they may not have been fully developed by their health IT vendor, or not fully implemented in time for data capture and reporting. Therefore, we are not proposing to require these two new measures in 2019, although eligible hospitals and CAHs may choose to report them and earn up to 5 bonus points for each measure. We are proposing to require these measures beginning with the EHR reporting period in 2020, and we are seeking public comment on this proposal. We note that due to varying State requirements, not all eligible hospitals and CAHs would be able to e-prescribe controlled substances, and thus these measures would not be available to them. For these reasons, we are proposing an exclusion for these two measures beginning with the EHR reporting period in 2020. The exclusion would provide that any eligible hospital or CAH that is unable to report the measure in accordance with applicable law would be excluded from reporting the measure, and the 5 points assigned to that measure would be redistributed to the e-Prescribing measure.

As the two new opioid measures become more broadly available in CEHRT, we are proposing each of the three measures within the e-Prescribing objective would be worth 5 points beginning in 2020. We note that requiring these two measures would add 10 points to the maximum total score as these measures would no longer be eligible for optional bonus points. To

maintain a maximum total score of 100 points, beginning with the EHR reporting period in 2020, we are proposing to reweight the e-Prescribing measure from 10 points down to 5 points, and reweight the Provide Patients Electronic Access to Their Health Information measure from 40 points down to 35 points as illustrated in the table below. We are proposing that if the eligible hospital or CAH qualifies for the e-Prescribing exclusion and is excluded from reporting all three of the measures associated with the e-Prescribing objective as described in section VIII.D.6.b. of the preamble of this proposed rule, the 15 points for the e-Prescribing objective would be redistributed evenly among the two measures associated with the Health Information Exchange objective and the Provide Patients Electronic Access to their Health Information measure by adding 5 points to each measure.

We are seeking public comment on the proposed distribution of points beginning with the EHR reporting period in 2020.

For the Health Information Exchange objective, we are proposing to change the name of the existing Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information, and proposing a new measure which combines the functionality of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. For more information about the proposed measure and measure changes, we refer readers to section VIII.D.6.c. of the preamble of this proposed rule. Eligible hospitals and CAHs would be required to report both of these measures, each worth 20 points toward their total Promoting Interoperability score. These measures are weighted heavily to emphasize the importance of sharing health information through interoperable exchange in an effort to promote care coordination and better patient outcomes. Similar to the two new measures in the e-Prescribing objective, the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure may not be available to all eligible hospitals and CAHs as it may not have been fully developed by their health IT vendor, or not fully implemented in time for an EHR reporting period in 2019. For these reasons, we are proposing an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure: Any eligible hospital or CAH that is unable to implement the measure for an EHR reporting period in 2019 would be excluded from having to report this measure.

In the event that an eligible hospital or CAH claims an exclusion for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points would be redistributed to the Support Electronic Referral Loops by Sending Health Information measure, and that measure would then be worth 40 points. We are seeking public comment on whether this redistribution is appropriate, or whether the points should be redistributed to other measures instead.

We are proposing to weigh the one measure in the Provider to Patient Exchange objective, Provide Patients Electronic Access to Their Health Information, at 40 points toward the total Promoting Interoperability score in 2019 and 35 points beginning in 2020. We are proposing that this measure would be weighted at 35 points beginning in 2020 to account for the two new opioid measures, which would be worth 5 points each beginning in 2020 as proposed above. We believe this objective and its associated measure get to the core of improved access and exchange of patient data in promoting interoperability and are the crux of the Medicare Promoting Interoperability Program. This exchange of data between health care provider and patient is imperative in order to continue to improve interoperability, data exchange and improved health outcomes. We believe that it is important for patients to have control over their own health information, and through this highly weighted objective we are aiming to show our dedication to this effort.

The measures under the Public Health and Clinical Data Exchange objective are reported using yes/no responses and thus cannot be scored based on performance. We are proposing that for this objective, the eligible hospital or CAH would be required to meet this objective in order to receive a score and be considered a meaningful user of EHR. We are proposing that the eligible hospital or CAH will be required to report the Syndromic Surveillance Reporting measure and one additional measure of the eligible hospital or CAH's choosing from the following: Immunization Registry Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, Electronic Reportable Laboratory Result Reporting. We are proposing an eligible hospital or CAH would receive 10 points for the objective if they attest a ''yes'' response for both the Syndromic Surveillance Reporting measure and one additional measure of their choosing. If the eligible hospital or CAH fails to report either one of the two measures required for this objective, the eligible hospital or CAH would receive a score of zero for the objective, and a total score of zero for the Promoting Interoperability Program. We understand that some hospitals may not be able to report the Syndromic Surveillance Reporting measure, or may not be able to report some of the other measures under this objective. Therefore, we are proposing to maintain the current exclusions for these measures that were finalized in previous rulemaking. If an eligible hospital or CAH claims an exclusion for one or both measures required for this objective, we are proposing the 10 points for this objective would be redistributed to the Provide Patients Electronic Access to their Health Information measure under the proposed Provider to Patient Exchange objective, making that measure worth 50 points in 2019 and 45 points beginning in 2020. Reporting more than two measures for this objective would not earn the eligible hospital or CAH any additional points. We refer readers to section VIII.D.6.e. of the preamble of this proposed rule in regards to the proposals for the current Public Health and Clinical Data Exchange objective and its associated measures.

The Stage 3 objective, Protect Patient Health Information, and its associated measure, Security Risk Analysis, would remain part of the program, but would no longer be scored as part of the objectives and measures, and would not contribute to the hospital's total score for the objectives and measures. To earn any score in the Promoting Interoperability Program, we are proposing eligible hospitals and CAHs would have to attest that they completed the actions included in the Security Risk Analysis measure at some point during the calendar year in which the EHR reporting period occurs. We believe the Security Risk Analysis measure involves critical tasks and note that the Health Insurance Portability and Accountability Act (HIPAA) Security Rule requires covered entities to conduct a risk assessment of their health care organization. This risk assessment will help eligible hospitals and CAHs comply with HIPAA's administrative, physical, and technical safeguards.[369] Therefore, we believe that

[369] *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html.*

every eligible hospital and CAH should already be meeting the requirements for this objective and measure as they are required by HIPAA. We still believe this objective and its associated measure is imperative in ensuring the safe delivery of patient health data. As a result, we would maintain the Security Risk Analysis measure as part of the Promoting Interoperability Program, but we would not score the measure. We are seeking public comment on whether the Security Risk Analysis measure should remain part of the program as an attestation with no associated score, or whether there should be points associated with this measure.

Similar to how eligible hospitals and CAHs currently submit data, the eligible hospital or CAH would submit their numerator and denominator data for each performance measure, and a yes/no response for each of the two reported measures under the proposed Public Health and Clinical Data Exchange objective. To earn a score greater than zero, in addition to completing the activities required by the Security Risk Analysis measure, the hospital would submit their complete numerator and denominator or yes/no data for all required measures. The numerator and denominator for each performance measure would then translate to a performance rate for that measure and would be applied to the total possible points for that measure. For example, the e-Prescribing measure is worth 10 points. A numerator of 200 and denominator of 250 would yield a performance rate of (200/250) = 80 percent. This 80 percent would be applied to the 10 total points available for the e-Prescribing measure to determine the performance score. A performance rate of 80 percent for the e-Prescribing measure would equate to a measure score of 8 points (performance rate * total possible measure points = points awarded toward the total PI score; 80 percent*10 = 8 points). These calculations and application to the total Promoting Interoperability score, as well as an example of how they would apply, are set out in the tables below.

When calculating the performance rates and measure and objective scores, we would generally round to the nearest whole number. For example if an eligible hospital or CAH received a score of 8.53 the nearest whole number would be 9. Similarly, if the eligible hospital or CAH received a score of 8.33 the nearest whole number would be 8. In the event that the eligible hospital or CAH receives a performance rate or measure score of less than 0.5, as long as the eligible hospital or CAH reported on at least one patient for a given measure, a score of 1 would be awarded for that measure. We believe this is the best method for the issues that might arise with the decimal points and is the easiest for computations.

In order to meet statutory requirements and HHS priorities, the eligible hospital or CAH would need to report on all of the required measures across all objectives in order to earn any score at all. Failure to report any required measure, or reporting a ''no'' response on a yes/no response measure, unless an exclusion applies would result in a score of zero. We acknowledge that, in this way, the program still maintains a certain ''all-or-nothing'' element. However, we are proposing to reduce the total number of required measures from 16 to 6, which we believe reduces burden, and to introduce a performance-based scoring methodology, which provides flexibility not provided under the existing Stage 3 scoring methodology. We are seeking public comment on the proposed requirement to report on all required measures, or whether reporting on a smaller subset of optional measures would be appropriate.

As stated earlier, an eligible hospital or CAH would need to earn a total Promoting Interoperability score of 50 points or more in order to satisfy the requirement to report on the objectives and measures of meaningful use under § 495.4. Our aim is that every patient has control of and access to their health data, and we believe that the proposed minimum Promoting Interoperability score is consistent with the current goals of the program that focus on interoperability and providing patients access to their health information. Our vision is for every eligible hospital and CAH to perform at 100 percent for all of the objectives and associated measures. However, we understand the constraints that health care providers face in providing care to patients and seek to provide flexibility for hospitals to create their own score using measures that are best suited to their practice. We also believe it is important to be realistic about what can be achieved. This required score may be adjusted over time as eligible hospitals and CAHs adjust to the new focus and scoring methodology of the Medicare Promoting Interoperability Program. We believe that the 50-point minimum Promoting Interoperability score provides the necessary benchmark to encourage progress in interoperability and also allows us to continue to adjust this benchmark as eligible hospitals and CAHs progress in health IT. We believe that this approach allows eligible hospitals and CAHs to achieve high performance in one area to offset performance in an area where a participant may need additional improvement. We are seeking public comment on whether this minimum score is appropriate, or whether a higher or lower minimum score would be better suited for the first year of this new scoring methodology.

We believe our proposal would increase flexibility and help to ease the burden on eligible hospitals and CAHs as well as provide additional options for meeting the required objectives. The proposed changes would allow the eligible hospital or CAH to focus on the measures that are more appropriate for the ways in which they deliver care to patients and types of services that they provide and improve on areas in which an eligible hospital or CAH might need some support. We believe that with this new proposed approach we are reducing administrative burden and allowing health care providers to focus more on their patients. The tables below illustrate our proposal for the new scoring methodology and an example of application of the proposed scoring methodology.

PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN 2019

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	10 points.
	Bonus: Query of Prescription Drug Monitoring Program (PDMP)	5 points bonus.
	Bonus: Verify Opioid Treatment Agreement	5 points bonus.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points.

PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN 2019—Continued

Objectives	Measures	Maximum points
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting (Required) *Choose one or more additional:* Immunization Registry Reporting. Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting.	10 points.

PROPOSED PERFORMANCE-BASED SCORING METHODOLOGY BEGINNING WITH EHR REPORTING PERIODS IN 2020

Objectives	Measures	Maximum points
e-Prescribing	e-Prescribing	5 points.
	Query of Prescription Drug Monitoring Program (PDMP)	5 points.
	Verify Opioid Treatment Agreement	5 points.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	20 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	35 points.
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting (Required) *Choose one or more additional:* Immunization Registry Reporting. Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting.	10 points.

We are seeking public comment on whether these measures are weighted appropriately, or whether a different weighting distribution, such as equal distribution across all measures would be better suited to this program and this proposed scoring methodology. We are also seeking public comment on other scoring methodologies such as the alternative we considered and described earlier in this section.

PROPOSED SCORING METHODOLOGY EXAMPLE

Objective	Measures	Numerator/ denominator	Performance rate	Score
e-Prescribing	e-Prescribing	200/250	80%	8 points.
	Query of Prescription Drug Monitoring Program	150/175	86%	5 bonus points.
	Verify Opioid Treatment Agreement	N/A	N/A	0 points.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information.	135/185	73%	15 points.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.	145/175	83%	17 points.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information.	350/500	70%	28 points.
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting (Required) *Choose one or more additional:* Immunization Registry Reporting. Electronic Case Reporting. Public Health Registry Reporting. Clinical Data Registry Reporting. Electronic Reportable Laboratory Result Reporting.	Yes	N/A	10 points.
Total Score				83 points.

As discussed earlier, if we do not finalize a new scoring methodology, we would maintain the current Stage 3 methodology with the same objectives, measures and requirements. However, we would include the 2 new opioid measures, if finalized. We refer readers to section VIII.D.6.b. and c. of the preamble of this proposed rule for a discussion of the measure proposals. The table below provides a general summary overview of what the Stage 3 objectives, measures, and reporting requirements would be if we do not finalize a new scoring methodology but we do finalize the two new opioid measures.

STAGE 3 OBJECTIVES, MEASURES, AND REPORTING REQUIREMENTS IF NEW SCORING METHODOLOGY IS NOT FINALIZED BUT TWO OPIOID MEASURES ARE FINALIZED

Objective	Measure (stage 3 threshold)	Reporting requirement
Protect Patient Health Information ..	Security Risk Analysis (Yes/No)	Report.
Electronic Prescribing	e-Prescribing (>25%)	Report all, but only meet the threshold for one.
	Verify Opioid Treatment Agreement (at least one patient) *	
	Query of Prescription Drug Monitoring Program (at least one patient). *	
Patient Electronic Access to Health Information.	Provide Patient Access (>50%)	Report and meet thresholds.
	Patient Specific Education (>10%)	
Coordination of Care Through Patient Engagement.	View, Download or Transmit (at least one patient)	Report all, but only meet the threshold for two.
	Secure Messaging (>5%).	
	Patient Generated Health Data (>5%).	
Health Information Exchange	Send a Summary of Care (>10%)	Report all, but only meet the threshold for two.
	Request/Accept Summary of Care (>10%).	
	Clinical Information Reconciliation (>50%).	
Public Health and Clinical Data Registry Reporting.	Immunization Registry Reporting	Report Yes/No to Three Registries.
	Syndromic Surveillance Reporting.	
	Case Reporting.	
	Public Health Registry Reporting.	
	Clinical Data Registry Reporting.	
	Electronic Reportable Laboratory Result Reporting.	

* These measures included only if finalized.

We also are seeking public comment on the feasibility of the new scoring methodology in 2019 and whether eligible hospitals and CAHs would be able to implement the new measures and reporting requirements under this performance-based scoring methodology. In addition, we note that in section VIII.D.8. of the preamble of this proposed rule, we are seeking public comment on how the Promoting Interoperability Program should evolve in future years regarding the future of the new scoring methodology and related aspects of the program.

We are proposing to codify the proposed new scoring methodology in a new paragraph (e) under § 495.24. We also are proposing to revise the introductory text of § 495.24 and the heading to paragraph (c) of this section to provide that the criteria specified in proposed new paragraph (e) would be applicable for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years. Further, we are proposing to revise the introductory text of § 495.24 and the heading to paragraph (d) of this section to provide that the criteria specified in paragraph (d) would be applicable for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting Interoperability Program for 2019 and subsequent years.

We are inviting public comments on our proposals.

6. Proposed Measures for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

a. Measure Proposal Summary Overview

As we noted in the preceding section in our discussion of the proposed scoring methodology for eligible hospitals and CAHs, in proposed § 495.24(e) we are proposing to make a number of changes to the Stage 3 measures under § 495.24(c) beginning in CY 2019 and subsequent years. As indicated in the scoring methodology section VIII.D.5. of the preamble of this proposed rule, we are proposing three new measures (Query of PDMP, Verify Opioid Treatment Agreement, and Support Electronic Referral Loops by Receiving and Incorporating Health Information) beginning with the EHR reporting period in CY 2019. We are proposing that the Query of PDMP and Verify Opioid Treatment agreement measures would be optional for EHR reporting periods in 2019 for eligible hospitals and CAHs and bonus points may be earned for reporting on them. We are proposing that the Support Electronic Referral Loops by Receiving and Incorporating Health Information would be required beginning in 2019 with an exclusion available. We are proposing to require the Query of PDMP and Verify Opioid Treatment Agreement measures beginning with the EHR reporting period in 2020, and we are seeking public comment on this proposal. Our intent is to ensure the measures better focus on the effective use of health IT, particularly for interoperability, and to address concerns stakeholders have raised through public forums and in public comments related to the perceived burden associated with the current measures in the program.

In addition, we continue to evaluate and consider broader HHS and CMS initiatives and priorities to advance health IT when considering and proposing new measures or changes to existing measures. CMS has identified certain priorities which align with the broader HHS initiatives encouraging increased use of prescription drug monitoring programs (PDMPs) to reduce inappropriate prescriptions, improve patient outcomes and allow for more informed prescribing practices.[370]

As we noted above, section 50413 of the Bipartisan Budget Act of 2018 amended section 1886(n)(3)(A) of the Act to eliminate the provision requiring more stringent measures of meaningful use. As a result, we can now offer additional flexibilities and burden reduction through various proposed methods including through combining, removing and/or adding measure options that are applicable to other care settings.

We are proposing to remove six measures. Two of the measures we are proposing to remove—Request/Accept Summary of Care and Clinical Information Reconciliation—would be replaced by the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which combines the functionalities and goals of the two

[370] *https://www.hhs.gov/opioids/about-the-epidemic/index.html*; *https://www.healthit.gov/opioids.*

Stage 3 measures it is replacing. Four of the measures—Patient-Specific Education; Secure Messaging; View, Download or Transmit; and Patient Generated Health Data—would be removed because they have proven burdensome to health care providers in ways that were unintended and detract from health care providers' progress on current program priorities.

While the measures would no longer need to be attested to if we finalize the proposal to remove them, health care providers may still continue to use the standards and functions of those measures based on their preferences and practice needs. We believe that this burden reduction would enable health care providers to focus on measures that further interoperability, the exchange of health care information, and advances of innovation in the use of CEHRT.

We also are proposing to add three new measures. For the e-Prescribing objective, we are proposing to add two new measures: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement, both of which support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescribing amongst health care providers and focusing on the advanced use of CEHRT. For the Health Information Exchange objective, we are proposing to add a new measure: Support Electronic Referral Loops by Receiving and Incorporating Health Information, which builds upon and replaces the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures, while furthering interoperability and the exchange of health information.

We are also proposing to rename some of the existing Stage 3 measures and objectives. We are proposing to rename the remaining Health Information Exchange measure, Send a Summary of Care, to Support Electronic Referral Loops by Sending Health Information. In addition, we are proposing to change the name of the Patient Electronic Access to Health Information objective to Provider to Patient Exchange, and proposing to rename the remaining measure, Provide Patient Access to Provide Patients Electronic Access to Their Health Information. We are proposing to eliminate the Coordination of Care Through Patient Engagement objective and all of its associated measures as described above. Finally, we are proposing to rename the Public Health and Clinical Data Registry Reporting objective to the Public Health and Clinical Data Exchange objective and are proposing to require attestation to the Syndromic Surveillance Reporting measure and at least one additional measure of the eligible hospital or CAH's choosing from the following: Immunization Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; Clinical Data Registry Reporting; and Electronic Reportable Laboratory Result Reporting.

Lastly, in connection with the scoring methodology proposed in section VIII.D.5. of the preamble of this proposed rule, we are proposing to remove the exclusion criteria from all of the Stage 3 measures we are retaining, except for the measures associated with the e-Prescribing objective, Public Health and Clinical Data Exchange objective and the new measures, which would include exclusion criteria. We are proposing to remove the exclusion criteria related to broadband availability because the Fixed Broadband Deployment Data from Federal Communications Commission (FCC) form 477 indicate no counties have less than 4 Mbps of broadband availability.[371] In addition, upon review of the 2016 Modified Stage 2 attestation data for eligible hospitals and CAHs, we found that no eligible hospital or CAH claimed an exclusion based on broadband availability. In addition, we do not believe that an exclusion based on the number of transitions or referrals received and patient encounters in which the provider has never previously encountered the patient is warranted for any of the measures associated with Health Information Exchange objective. This exclusion applies for the Stage 3 Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure. We reviewed the 2016 Modified Stage 2 attestation data for the Medication Reconciliation measure, which the Clinical Information Reconciliation measure is based on and found that all eligible hospitals and CAHs who attested successfully reported this measure, although we note an exclusion was not available for this measure.[372]

In addition, we are seeking public comment on a potential new measure Health Information Exchange Across the Care Continuum under the Health Information Exchange objective. Under this proposed measure, an eligible hospital or CAH would send an electronic summary of care record, or receive and incorporate an electronic summary of care record, for transitions of care and referrals with a provider of care other than an eligible hospital or CAH. The measure would include health care providers in care settings including but not limited to long term care facilities, and post-acute care providers such as skilled nursing facilities, home health, and behavioral health settings.

We are proposing that all of the measure proposals in this section VIII.D.6. of the preamble of this proposed rule would apply to eligible hospitals and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, including Medicare-only and dual-eligible eligible hospitals and CAHs. We are not proposing to apply these measure proposals to Medicaid-only eligible hospitals that submit an attestation to their State Medicaid agency for the Medicaid Promoting Interoperability program. Instead, as discussed in section VIII.D.7. of the preamble of this proposed rule, we are proposing to give States the option to adopt these measure proposals along with the proposed performance-based scoring methodology discussed in section VIII.D.5. of the preamble of this proposed rule for their Medicaid Promoting Interoperability Program through their State Medicaid HIT Plans.

The table below provides a summary of these measures proposals.

[371] *https://www.fcc.gov/general/broadband-deployment-data-fcc-form-477.*

[372] *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PUF.html.*

SUMMARY OF MEASURES PROPOSALS

Measure status	Measure
Measures retained from Stage 3 with no modifications *	e-Prescribing.
	Immunization Registry Reporting.
	Syndromic Surveillance Reporting.
	Electronic Case Reporting.
	Public Health Registry Reporting.
	Clinical Data Registry Reporting.
	Electronic Reportable Laboratory Result Reporting.
Measures retained from Stage 3 with modifications	Send a Summary of Care (Proposed Name: Supporting Electronic Referral Loops by Sending Health Information).
	Provide Patient Access (Proposed Name: Provide Patients Electronic Access to Their Health Information).
Removed measures	Request/Accept Summary of Care.
	Clinical Information Reconciliation.
	Patient-Specific Education.
	Secure Messaging.
	View, Download or Transmit.
	Patient Generated Health Data.
New measures	Query of Prescription Drug Monitoring Program (PDMP).
	Verify Opioid Treatment Agreement.
	Support Electronic Referral Loops by Receiving and Incorporating Health Information.

* Security Risk Analysis is retained, but not included as part of the proposed scoring methodology.

We note the proposals under the Health Information Exchange objective require only consolidation of existing workflows and actions, while certification criteria and standards remain the same as finalized in the October 16, 2015 final rule titled ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (80 FR 62601 through 62759), hereafter referred to as the ''ONC 2015 Edition final rule.'' Therefore, we believe it would not take the full 18 to 24 months of development and implementation time to transition as indicated in the 2015 EHR Incentive Programs final rule (80 FR 62875) and could potentially be implemented for an EHR reporting period in 2019.

As we discussed in section VIII.D.5. of the preamble of this proposed rule, we are proposing that if we do not finalize a new scoring methodology, we would maintain the current Stage 3 methodology with the same objectives, measures and requirements, but we would include the two new opioid measures, if they are finalized. In addition, if we do not finalize a new scoring methodology, the proposals to remove objectives and measures as well as proposals to change objective and measure names would no longer be applicable.

We are seeking public comment on these proposals.

b. Measure Proposals for the e-Prescribing Objective

In the 2015 EHR Incentive Programs final rule, since electronic prescribing of controlled substances had further matured and was feasible in many States, we allowed eligible hospitals and CAHs to include controlled substances under the definition of permissible prescriptions for the e-Prescribing objective, as long as they were included uniformly across patients and all available schedules and in accordance with applicable law (80 FR 62834).

We believe it is important to consider other requirements specific to electronic prescribing of controlled substances for health care providers to take into account and how this may interact with the proposals under this rulemaking. CMS is committed to combatting the opioid epidemic by making it a top priority for the agency and aligning its efforts with the HHS opioid initiative to combat misuse and promote programs that support treatment and recovery support services. The HHS five-point Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;
- Target the availability and distribution of overdose-reversing drugs to ensure the provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

CMS' strategy includes reducing the risk of opioid use disorders, overdoses, inappropriate prescribing practices and drug diversion. We have identified two new measures which align with the broader HHS efforts to increase the use of PDMPs to reduce inappropriate prescriptions, improve patient outcomes and promote more informed prescribing practices.

We are proposing to add two new measures to the e-Prescribing objective under § 495.24(5)(iii) that are based on electronic prescribing for controlled substances (EPCS): Query of PDMP, and Verify Opioid Treatment Agreement. These measures build upon the meaningful use of CEHRT as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we are proposing to define opioids as Schedule II controlled substances under 21 CFR 1308.12, as

they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. We are also proposing to apply the same policies for the existing e-Prescribing measure under § 495.24(e)(5)(iii) to both the Query of the PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. Eligible hospitals and CAHs have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law (80 FR 62834; 81 FR 77227). However, because the intent of these two new measures is to improve prescribing practices for controlled substances, eligible hospitals and CAHs would have to include Schedule II opioid prescriptions in the numerator and denominator or claim the applicable exclusion.

In the event we finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, that eligible hospitals and CAHs that claim the broader exclusion under the e-Prescribing measure would automatically receive an exclusion for all three of the measures under the e-Prescribing objective; they would not have to also claim exclusions for the other two measures Query of PDMP and Verify Opioid Treatment Agreement.

In the event we do not finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, but we do finalize the proposed measures of Query of Prescription Drug Monitoring Program and Verify Opioid Treatment Agreement under the e-Prescribing objective, we would continue to apply the Stage 3 requirements finalized in previous rulemaking, and we are proposing that eligible hospitals and CAHs would be required to report all three measures under the e-Prescribing objective, but would only be required to meet the threshold for the e-Prescribing measure, or claim an exclusion. In addition, in the event the new scoring methodology we are proposing is not finalized, we would retain the existing e-Prescribing measure threshold of 25 percent under § 495.24(c)(2)(ii).

We are requesting public comments on these proposals.

(1) Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP)

A PDMP is an electronic database that tracks prescriptions of controlled substances at the State level. PDMPs play an important role in patient safety by assisting in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Querying the PDMP is important for tracking the prescribed controlled substances and improving prescribing practices. The ONC, the Centers for Disease Control and Prevention (CDC), the Department of Justice (DOJ), and the Substance Abuse and Mental Health Services Administration (SAMHSA) have had integral roles in the integration and expansion of PMDPs with health information technology systems. For example, the ONC and the SAMHSA collaboratively led the ''Enhancing Access'' project to improve health care provider access to PDMP data utilizing health IT.[373] Likewise, the CDC conducted a process and outcome evaluation of the PDMP EHR Integration and Interoperability Expansion (PEHRIIE) program funded by SAMHSA for nine States between FY 2012 and 2016. The PEHRIIE program goals were to integrate PDMPs into health IT and improve the comprehensiveness of PDMPs through initiating and/or improving interstate data exchange.[374] In addition, the Bureau of Justice Assistance's Harold Rogers Prescription Monitoring Program supports Prescription Drug Monitoring Program Information Exchange (PMIX) through funding, and the goal of PMIX is to help States implement a cost-effective solution to facilitate interstate data sharing among PDMPs.[375] Integration of the PDMP with health information technology systems supports improves access to PDMP data, minimizes changes to current workflow and overall burden and optimizes prescribing practices. The intent of the Query of the PDMP measure is to build upon the current PDMP initiatives from Federal partners focusing on prescriptions generated and dispensing of opioids.

Proposed Measure Description: 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 is conducted, except where prohibited and in accordance with applicable law.

CMS recognizes both the utility and value of addressing PDMP EHR integration and further recognizes the majority of States mandate use of State prescription monitoring programs (PMPs) requiring prescribers/dispensers to access PMP.[376] According to the CDC, State-level policies that enhance PDMPs or regulate pain clinics helped several States drive down opioid prescriptions and overdose deaths.[377] We are also further aware of the varying integration approaches underway including efforts to integrate a State PDMP into a health information exchange or electronic health record (EHR) or other efforts to enhance a user interface of some type, such as risk assessment tools or red flags. We note Federal evaluation resources available to inform integration efforts[378] and believe integration is critical for enhancing provider workflow, access to critical PDMP data, and improving clinical care including prescription management.

We are proposing that the query of the PDMP for prescription drug history must be conducted prior to the electronic transmission of the Schedule II opioid prescription. Eligible hospitals and CAHs would have flexibility to query the PDMP using CEHRT in any manner allowed under their State law.

Although the query of the PDMP may currently be burdensome for some health care providers as part of their current workflow practice, we believe the query of a PDMP is beneficial to optimal prescribing practices and foresee progression toward fully automated queries of the PDMP building upon the current initiatives at the State level.

We are proposing to include in this measure all permissible prescriptions and dispensing of Schedule II opioids regardless of the amount prescribed during an encounter in order for eligible hospitals and CAHs to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. However, we are proposing that multiple Schedule II opioid prescriptions prescribed on the same date by the same eligible hospital or CAH would not require multiple

[373] *https://www.healthit.gov/PDMP* and *https://www.healthit.gov/sites/default/files/work_group_document_integrated_paper_final_0.pdf.*

[374] *https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.*

[375] *https://www.bja.gov/funding/Category-5-awards.pdf.*

[376] *http://www.namsdl.org/library/14D3122C-96F5-F53E-E8F23E906B4DE09D/.*

[377] *https://www.cdc.gov/drugoverdose/policy/successes.html.*

[378] *https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.*

queries of the PDMP. For example, if more than one opioid is prescribed by the eligible hospital or CAH, only one query would have to be performed for this measure. We have also considered that in most cases, only one instance of querying the PDMP may be necessary or appropriate for each hospital stay, and querying the PDMP on each day a medication is prescribed may be burdensome for providers. We are requesting comment on whether we should further refine the measure to limit queries of the PDMP to once during the stay regardless of whether multiple eligible medications are prescribed during this time.

Denominator: Number of Schedule II opioids electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.

Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period.

We are proposing that the exclusion criteria would be limited to prescriptions of controlled substances as the measure action is specific to prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions. In the event we finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, an additional exclusion would be available beginning in 2020 for eligible hospitals and CAHs that could not report on this measure in accordance with applicable law.

We also understand that PDMP integration is not currently in widespread use for CEHRT, and many eligible hospitals and CAHs may require additional time and workflow changes at the point of care before they can meet this measure without experiencing significant burden. For instance, many eligible hospitals and CAHs will likely need to manually enter data into CEHRT to document the completion of the query of the PDMP action. In addition, some eligible hospitals and CAHs may also need to conduct manual calculation of the measure. Even for those eligible hospitals and CAHs that have achieved successful integration of a PDMP with their EHR, this measure may not be machine calculable, for instance, in cases where the eligible hospital or CAH follows a link within the EHR to a separate PDMP system. For the purposes of meeting this measure, we also understand that there are no existing certification criteria for the query of a PDMP. However, we believe that the use of structured data captured in the CEHRT, can support querying a PDMP through the broader use of health IT. We are seeking public comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and if such criteria were to be adopted, on what timeline should CMS require their use to meet this measure.

We note that the NCPDP SCRIPT 2017071 standard for e-prescribing is now available and can help to support PDMP and EHR integration. We are seeking public comment especially from health care providers and health IT developers on whether they believe use of this standard can support eligible hospitals and CAHs seeking to report on this measure, and whether HHS should encourage use of this standard through separate rulemaking.

We are seeking public comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden.

In including EPCS as a component of the measure we are proposing, we acknowledge and are seeking input on perceived and real technological barriers as part of its effective implementation including but not limited to input on two-factor authentication and on the effective and appropriate uses of technology, including the use of telehealth modalities to support established patient provider relationships subsequent to in-person visit(s) and for prescribing purposes.

We also are requesting comment on limiting the exclusion criteria to electronic prescription for controlled substances and whether there are circumstances which may justify any additional exclusions for the Query of PDMP measure and what those circumstances might be.

We note that under the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, measures would not have required thresholds for reporting. Therefore, if the proposed scoring methodology and this measure were finalized, this measure would not have a reporting threshold. In the event we do not finalize the proposed scoring methodology, we are proposing a threshold of at least one prescription for this new measure. We believe a threshold of at least one prescription is appropriate because varying State laws related to integration of the PDMP into CEHRT can lead to differing standards for querying.

We are also proposing that in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3) and 170.315(a)(10)(ii).

We are proposing to codify the Query of the PDMP measure at § 495.24(e)(5)(iii)(B).

We are inviting public comment on the proposals.

(2) Proposed Measure: Verify Opioid Treatment Agreement

The intent of this measure is for eligible hospitals and CAHs to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days. We believe seeking to identify an opioid treatment agreement will further efforts to coordinate care between health care providers and foster a more informed review of patient therapy. The intent of the treatment agreement is to clearly outline the responsibilities of both patient and health care provider in the treatment plan. Such a treatment plan can be integrated into care coordination and care plan activities and documents as discussed and agreed upon by the patient and health care provider. An opioid treatment agreement is intended to support and to enable further coordination and the sharing of substance use disorder (SUD) data with consent, as may be required of the individual.

According to the American Journal of Psychiatry article *Prescription Opioid Misuse, Abuse, and Treatment in the United States: An Update,*[379] patient provider treatment agreements are part of the recommendations to enhance efforts to prevent opioid abuse per the Office of the National Drug Control Policy's National Drug Control Strategy.[380] The article further indicates that the treatment agreement can be

[379] Brady KT, McCauley JL, Back SE. Prescription Opioid Misuse, Abuse, and Treatment in the United States: An Update American Journal of Psychiatry, Volume 173, Issue 1, January 01, 2016, pp. 18–26. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4782928/.*

[380] *https://obamawhitehouse.archives.gov/ondcp/policy-and-research/ndcs.*

beneficial as it provides clear information for the agreed upon pain management plan, preventing misconceptions.

An article in Pain Medicine, *Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain* also includes treatment agreements as part of the ''Ten Steps of Universal Precautions in Pain Medicine'' which are stated to be recommended starting points for discussion in the treatment of chronic pain.[381]

We also understand from stakeholder feedback during listening sessions that there are varied opinions regarding opioid treatment agreements amongst health care providers. Some are supportive of their use, indicating that treatment agreements are an important part of the prescription of opioids for pain management, and help patients understand their role and responsibilities for maintaining compliance with terms of the treatment. Other health care providers object to their use citing ethical concerns, and creation of division and trust issues in the health care provider–patient relationship. Other concerns stem from possible disconnect between the language and terminology used in the agreement and the level of comprehension on the part of the patient. Because of the debate among practitioners, we are requesting comment on the challenges this proposed measure may create for health care providers, how those challenges might be mitigated, and whether this measure should be included as part of the Promoting Interoperability Program. We also acknowledge challenges related to prescribing practices and multiple State laws which may present barriers to the uniform implementation of this proposed measure. We are seeking public comment on the challenges and concerns associated with opioid treatment agreements and how they could impact the feasibility of the proposal.

Proposed Measure Description: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into CEHRT.

We understand from listening sessions with stakeholders that eligible hospitals and CAHs typically do not prescribe opioid medications for more than a few days if at all. In consideration of this low volume of opioid prescriptions, we are proposing this measure would include all Schedule II opioids prescribed for a patient electronically using CEHRT by the eligible hospital or CAH during the EHR reporting period, as well as any Schedule II opioid prescriptions identified in the patient's medication history request and response transactions during a 6 month look-back period, where the total number of days for which a Schedule II opioid was prescribed for the patient is at least 30 days.

There also may be burdens specific to identifying the existence of a treatment agreement which could require additional time and changes to existing workflows, determining what constitutes a treatment agreement due to a lack of a definition, standard or electronic format and manual calculation of the measure. In addition, limitations in the completeness of care team information may limit the ability of an eligible hospital and CAH to identify all potential sources for querying and obtaining information on a treatment agreement for a specific patient. There are currently pilots in development focused on increasing connectivity and data exchange among health care providers to better integrate behavioral health information, for instance, pilots taking place as part of the Federal Demonstration Program for Certified Community Behavioral Health Clinics (CCBHCs) [382] includes criteria on how CCBHCs should use health IT to coordinate services and track data on quality measures. Participants in such pilots would potentially have the means necessary to leverage health IT connectivity to query behavioral health data resources and health care providers within their region to identify the existence of an opioid treatment agreement and to seamlessly integrate patient information received into the care plan for the patient. We are seeking public comment on other similar pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning.

We are proposing that the 6-month look-back period would begin on the date on which the eligible hospital or CAH electronically transmits its Schedule II opioid prescription using CEHRT. For example, all of the following prescriptions would be counted for this measure: A Schedule II opioid electronically prescribed for a patient for a duration of five days by the eligible hospital or CAH using CEHRT during the EHR reporting period, and four prior prescriptions for any Schedule II opioid prescribed by the patient's physician (each for a duration of seven days) as identified in the patient's medication history request and response transactions during the 6-month period preceding the date on which the eligible hospital or CAH electronically transmits its Schedule II opioid prescription using CEHRT. In this example, the total number of days for which a Schedule II opioid was prescribed for the patient would equal 33 cumulative days.

We are proposing a 6-month look-back period in order to identify more egregious cases of potential overutilization of opioids and to cover timeframes for use outside the EHR reporting period. In addition, we are proposing that the 6-month look-back period would utilize at a minimum the industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at 45 CFR 170.205(b)(2). As ONC has stated (80 FR 62642), adoption of the requirements for NCDCP SCRIPT v10.6 does not preclude developers from incorporating and using technology standards or services not required by regulation in their health IT products.

We are not proposing to define an opioid treatment agreement as a standardized electronic document; nor are we proposing to define the data elements, content structure, or clinical purpose for a specific document to be considered a ''treatment agreement.'' For this measure, we are seeking public comment on what characteristics should be included in an opioid treatment agreement and incorporated into CEHRT, such as clinical data, information about the patient's care team, and patient goals and objectives, as well as which functionalities could be utilized to accomplish the incorporation of this information. We note that a variety of standards available in CEHRT might support the electronic exchange of opioid abuse related treatment data, such as use of the Consolidated Clinical Document Architecture (CCDA) care plan template that is currently optional in CEHRT. We are also seeking public comment on methods or processes for incorporation of the treatment agreement into CEHRT, including which functionalities could

[381] Gourlay DL, Heit HA, Almahrezi A. ''Universal Precautions in Pain Medicine: A Rational Approach to the Treatment of Chronic Pain.'' Pain Medicine, Volume 6, Issue 2, 1 March 2005, pp. 107–112. Available at: *https://academic.oup.com/painmedicine/article/6/2/107/1819946.*

[382] *https://www.samhsa.gov/section-223.*

be utilized to accomplish this. We are seeking public comment on whether there are specific data elements that are currently standardized that should be incorporated via reconciliation and if the ''patient health data capture'' functionality could be used to incorporate a treatment plan that is not a structured document with structured data elements.

Denominator: Number of unique patients for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period and the total duration of Schedule II opioid prescriptions is at least 30 cumulative days as identified in the patient's medication history request and response transactions during a 6-month look-back period.

Numerator: The number of unique patients in the denominator for whom the eligible hospital or CAH seeks to identify a signed opioid treatment agreement and, if identified, incorporates the agreement in CEHRT.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period.

We are proposing that the exclusion criteria would be limited to prescriptions of controlled substances as the measure action is specific to electronic prescriptions of Schedule II opioids only and does not include any other types of electronic prescriptions. In the event we finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, an additional exclusion would be available beginning in 2020 for eligible hospitals and CAHs that could not report on this measure in accordance with applicable law. We are requesting public comment on limiting the exclusion criteria to electronic prescriptions for controlled substances and whether there are circumstances which may require an additional exclusion for the Verify Opioid Treatment Agreement measure and what those circumstances might be.

We note that under the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, measures would not have required thresholds for reporting. Therefore, if the proposed scoring methodology and measure were finalized, this measure would not have a reporting threshold. In the event we do not finalize the proposed scoring methodology, but we finalize this proposed measure, we are proposing a threshold of at least one unique patient for this new measure. We believe a threshold of at least one unique patient is appropriate to account for the varying support for the use of opioid treatment agreements and acknowledging that not all patients who receive at least 30 cumulative days of Schedule II opioids would have a treatment agreement in place. We also note there are medical diagnoses and conditions that could necessitate prescribing Schedule II opioids for a cumulative period of more than 30 days.

We are also proposing that, in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(b)(3), 170.315(a)(10) and 170.205(b)(2).

As discussed above, we recognize that many providers are only beginning to adopt EPCS at this time. While we are proposing two new measures which combine EPCS with other actions, we are requesting comment on whether we should explore adoption of a measure focused only on the number of Schedule II opioids prescribed and the successful use of EPCS for permissible prescriptions electronically prescribed. We are seeking public comment about the feasibility of such a measure, and whether stakeholders believe this would help to encourage broader adoption of EPCS.

We are proposing to codify the Verify Opioid Treatment Agreement measure at § 495.24(e)(5)(iii)(C).

We are seeking public comment on the proposals for this measure.

c. Measure Proposals for the Health Information Exchange (HIE) Objective

The Health Information Exchange measures for eligible hospitals and CAHs hold particular importance because of the role they play within the care continuum. In addition, these measures encourage and leverage interoperability on a broader scale and promote health IT-based care coordination. However, through our review of existing measures, we determined that we could potentially improve the measures to further reduce burden and better focus the measures on interoperability in provider to provider exchange. Such modifications would address a number of concerns raised by stakeholders including:

- Supporting the implementation of effective health IT supported workflows based on a specific organization's needs;
- Reducing complexity and burden associated with the manual tracking of workflows to support health IT measures; and
- Emphasizing within these measures the importance of using health IT to support closing the referral loop to improve care coordination.

The Health Information Exchange objective includes three measures under § 495.24(e)(6)(ii), and we believe we can potentially improve each to streamline measurement, remove redundancy, reduce complexity and burden, and address stakeholders' concerns about the focus and impact of the measures on the interoperable use of health IT.

As discussed in section VIII.D.6.a. of the preamble of this proposed rule, we are proposing to remove the exclusions from all three of the measures associated with the Health Information Exchange objective under § 495.24(c)(7)(iii) in proposed § 495.24(e)(6). However, in the event we finalize the new scoring methodology we are proposing, eligible hospitals and CAHs would be able to claim an exclusion under the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure as indicated in section VIII.D.6.c.(4) of the preamble of this proposed rule.

We are proposing several changes to the current measures under the Stage 3 Health Information Exchange objective. First, we are proposing to change the name of Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information. We also are proposing to remove the current Stage 3 Clinical Information Reconciliation measure and combine it with the Request/Accept Summary of Care measure to create a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information. This proposed new measure would include actions from both the current Request/Accept Summary of Care measure and Clinical Information Reconciliation measure and focus on the exchange of the health care information while reducing the administrative burden of reporting on two separate measures.

As discussed earlier in the proposed rule, in the event we do not finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, we would maintain the current Health Information Exchange objective, associated measures and exclusions under § 495.24(c)(7) as described in section VIII.D.5. of the preamble of this proposed rule and as outlined in the table in that section which describes Stage 3 objectives and measures if new scoring methodology is not finalized.

We are seeking public comment on these proposals.

(1) Proposed Modifications To Send a Summary of Care Measure

We are proposing to change the name of the Send a Summary of Care measure at 42 CFR 495.24(c)(7)(ii)(A) to Support Electronic Referral Loops by Sending Health Information at 42 CFR 495.24(e)(6)(ii)(A), to better reflect the emphasis on completing the referral loop and improving care coordination. We are proposing to change the measure description only to remove the previously defined threshold from Stage 3, in alignment with our proposed implementation of a performance-based scoring system, to require that the eligible hospital or CAH create a summary of care record using CEHRT and electronically exchange the summary of care record for at least one transition of care or referral.

Proposed name and measure description: Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Through public comment and stakeholder correspondence, we have become aware that, in the health care industry, there is some misunderstanding of the scope of transitions and referrals which must be included in the denominator of this measure. In the rulemaking for Stages 2 and 3 (77 FR 54013 through 54021, 80 FR 62852 through 62862), we noted the denominator for this measure includes all transitions of care and referrals from an inpatient setting and all transitions or referrals from an emergency department where follow up care is ordered by an authorized provider. In the event that an eligible hospital or CAH is the recipient of a transition of care or referral, and subsequent to providing care the eligible hospital or CAH transitions or refers the patient back to the referring provider of care, this transition of care should be included in the denominator of the measure for the eligible hospital or CAH. We expect this will help build upon the current provider to provider communication via electronic exchange of summary of care records created by CEHRT required under this measure, further promote interoperability and care coordination with additional health care providers, and prevent redundancy in creation of a separate measure.

In the past, stakeholders have raised concerns that the summary care records shared according to the CCDA standard included excessive information not relevant to immediate care needs, which increased burden on health care providers. Under the ONC Health IT Certification Program, certified EHR technology must have the capability to exchange all of the information in the Common Clinical Data Set (CCDS) as part of a summary care record structured according to the CCDA standard. We previously finalized in the Stage 2 final rule (77 FR 53991 through 53993) that health care providers must transmit all of the CCDS information as part of this summary care record, if known, and that health care providers must always transmit information about the problem list, medications, and medication allergies, or validate that this information is not known.

As finalized in the 2015 EHR Incentive Programs final rule (80 FR 62852 through 62861), our policy allows health care providers to constrain the information in the summary care record to support transitions of care. For instance, we encouraged health care providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the health care provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

We also wish to encourage eligible hospitals and CAHs to use the document template available within the CCDA which contains the most clinically relevant information that may be required by the recipient of the transition or referral. Accordingly, we are proposing that eligible hospitals and CAHs may use any document template within the CCDA standard for purposes of the measures under the Health Information Exchange objective. While eligible hospitals' and CAHs' CEHRT must be capable of sending the full CCDA upon request, we believe this additional flexibility will help support efforts to ensure the information supporting a transition is relevant.

For instance, when the eligible hospital or CAH is referring to another health care provider, the recommended document is the ''Referral Note,'' which is designed to communicate pertinent information from a health care provider who is requesting services of another health care provider of clinical or nonclinical services. When the receiving health care provider sends back the information, the most relevant CCDA document template may be the ''Consultation Note,'' which is generated by a request from a clinician for an opinion or advice from another clinician. However, eligible hospitals and CAHs may choose to utilize other documents within the CCDA to support transitions, for instance the ''Discharge Summary'' document. For more information about the CCDA and associated templates, we refer readers to: *http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_CCDA_CLINNOTES_R1_DSTU_R2.1_2015AUG.zip*.

We note that under the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, measures would not have required thresholds for reporting; therefore, if the new scoring methodology and measure were finalized, this measure would not have a reporting threshold. In the event we do not finalize the proposed scoring methodology, we would maintain the current Stage 3 requirements finalized in previous rulemaking. Therefore, eligible hospitals and CAHs would be required report on the Stage 3 Send a Summary of Care measure under the Health Information Exchange objective codified at § 495.24(c)(7)(ii)(A).

We are inviting public comment on the measure proposals.

(2) Proposed Removal of the Request/Accept Summary of Care Measure

We are proposing to remove the Request/Accept Summary of Care measure at § 495.24(c)(7)(ii)(B) under the proposed § 495.24(e)(6) based on our analysis of the existing measure and in response to stakeholder input.

Through review of implementation practices based on stakeholder feedback, we believe that the existing Request/Accept Summary of Care measure is not feasible for machine calculation in the majority of cases. The intent of the measure is to identify when health care providers are engaging with other providers of care or care team members to obtain up-to-date patient health information and to subsequently incorporate relevant data into the patient record. However, stakeholders have noted the measure specification does not effectively further this purpose. Specifically, the existing measure specification results in unintended consequences where health care providers implement either:

- A burdensome workflow to document the manual action to request

or obtain an electronic record, for example, clicking a check box to document each phone call or similar manual administrative task, or

• A workflow which is limited to only querying internal resources for the existence of an electronic document.

Neither of these two implementation options is desirable when the intent of the measure is to incentivize and encourage eligible hospitals and CAHs to implement effective workflows to identify, receive, and incorporate patient health information from other providers of care into the patient record.

In addition, our analysis identified that the definition of ''incorporate'' within the Request/Accept Summary of Care measure is insufficient to ensure an interoperable result. In the 2015 EHR Incentive Programs final rule at 80 FR 62860, we did not define ''incorporate'' as we believed it would vary based on an eligible hospital's or CAH's workflows, patient population, and the referring provider of care. In addition, we noted that the information could be included as an attachment, as a link within the EHR, as imported structured data or reconciled within the record and not exclusively performed through use of CEHRT. Further, stakeholder feedback highlights the fact that the requirement to incorporate data is insufficiently clear regarding what data must be incorporated.

Our intention was that ''incorporate'' would relate to the workflows undertaken in the process of clinical information reconciliation further defined in the Clinical Information Reconciliation measure (80 FR 62852 through 62862). Taken together, the three measures under the Health Information Exchange objective were intended to support the referral loop through sending, receiving, and incorporating patient health data into the patient record. However, stakeholder feedback on the measures suggests that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination workflows. Further, stakeholders noted that when approached separately, the incorporate portion of the Request/Accept Summary of Care measure is both inconsistent with and redundant to the Clinical Information Reconciliation measure which causes unnecessary burden and duplicative measure calculation.

We are requesting public comments on our proposal to remove the Request/Accept Summary of Care measure.

(3) Proposed Removal of the Clinical Information Reconciliation Measure

We are proposing to remove the Clinical Information Reconciliation measure at § 495.24(c)(7)(ii)(C) from the new measures at proposed § 495.24(e)(6) to reduce redundancy, complexity, and provider burden.

As discussed in the prior subsection, we believe the Clinical Information Reconciliation measure is redundant in regard to the requirement to ''incorporate'' electronic summaries of care in light of the requirements of the Request/Accept Summary of Care measure. In addition, the measure is not fully health IT based as the exchange of health care information is not required to complete the measure action and the measure specification is not limited to only the reconciliation of electronic information in health IT supported workflows. We stated in the 2015 EHR Incentive Programs final rule at 80 FR 62861 that the clinical information reconciliation process could involve both automated and manual reconciliation to allow the receiving health care provider to work with both electronic data received as well as the patient to reconcile their health information. Further, stakeholder feedback from hospitals, clinicians, and health IT developers indicates that because the measure is not fully based on the use of health IT to meet the measurement requirements, eligible hospitals and CAHs must engage in burdensome tracking of manual workflows. While the overall activity of clinical information reconciliation supports quality patient care and should be a part of effective clinical workflows, the process to record and track each individual action places unnecessary burden on eligible hospitals and CAHs.

We are inviting public comment on our proposal to remove the Clinical Information Reconciliation measure.

(4) Proposed New HIE Measure: Support Electronic Referral Loops by Receiving and Incorporating Health Information

We are proposing to add the following new measure for inclusion in the Health Information Exchange objective at § 495.24(e)(6)(ii)(B): Support Electronic Referral Loops by Receiving and Incorporating Health Information. This measure would build upon and replace the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures.

Proposed measure name and description: Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, mediation allergy, and current problem list.

We are proposing to combine two existing measures, the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure, in this new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to focus on the exchange of health care information as the current Clinical Information Reconciliation measure is not reliant on the exchange of health care information nor use of CEHRT to complete the measure action. We are not proposing to change the actions associated with the existing measures; rather, we are proposing to combine the two measures to focus on the exchange of the health care information, reduce administrative burden, and streamline and simplify reporting.

CMS and ONC worked together to define the following for this measure:

Denominator: Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.

Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

For the proposed measure, the denominator would increment on the receipt of an electronic summary of care record after the eligible hospital or CAH engages in workflows to obtain an electronic summary of care record for a transition, referral or patient encounter in which the health care provider has never before encountered the patient. The numerator would increment upon

completion of clinical information reconciliation of the electronic summary of care record for medications, medication allergies, and current problems. The eligible hospital or CAH would no longer be required to manually count each individual non-health-IT-related action taken to engage with other providers of care and care team members to identify and obtain the electronic summary of care record. Instead, the proposed measure would focus on the result of these actions when an electronic summary of care record is successfully identified, received, and reconciled with the patient record. We believe this approach would allow eligible hospitals and CAHs to determine and implement appropriate workflows supporting efforts to receive the electronic summary of care record consistent with the implementation of effective health IT information exchange at an organizational level.

Finally, we are proposing to apply our existing policy 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, and the eligible hospital or CAH may count the reconciliation in the numerator without completing a redundant or duplicate update to the record. We welcome public comment on methods by which this specific action could potentially be electronically measured by the provider's health IT system—such as incrementing on electronic signature or approval by an authorized provider—to mitigate the risk of burden associated with manual tracking of the action.

We welcome public comment on these proposals. In addition, we are seeking public comment on methods and approaches to quantify the reduction in burden for eligible hospitals and CAHs implementing streamlined workflows for this proposed measure. We also are seeking public comment on the impact these proposals may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, we are seeking public comment on whether ONC should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification. Finally, we are seeking public comment on whether this proposed new measure that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures should be adopted, or whether either or both of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure.

In the event we finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, above, an exclusion would be available for eligible hospitals and CAHs that could not implement the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for an EHR reporting period in CY 2019.

We note that under the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, measures would not have required thresholds for reporting. Therefore, if the proposed scoring methodology and measure were finalized, this measure would not have a reporting threshold. In the event we do not finalize the proposed new scoring methodology, we would maintain the current Stage 3 requirements finalized in previous rulemaking. Therefore, eligible hospitals and CAHs would be required report on the Stage 3 Request/Accept Summary of Care measure and Clinical Information Reconciliation measures under the Health Information Exchange objective codified at § 495.24(c)(7)(ii)(B) and (C).

We also are proposing that, in order to meet this measure, an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 45 CFR 170.315(g)(1) and (g)(2).

d. Measure Proposals for the Provider to Patient Exchange Objective

The Provider to Patient Exchange objective for eligible hospitals and CAHs builds upon the goal of improved access and exchange of patient health information, patient centered communication and coordination of care using CEHRT. We are proposing a new scoring methodology in section VIII.D.5. of the preamble of this proposed rule, under which (in section VIII.D.6. of the preamble of this proposed rule) which we are proposing to rename the Patient Electronic Access to Health Information objective to Provider to Patient Exchange, remove the Patient Specific Education measure and rename the Provide Patient Access measure to Provide Patients Electronic Access to Their Health Information. In addition, we are proposing to remove the Coordination of Care through Patient Engagement objective and all associated measures. The existing Stage 3 Patient Electronic Access to Health Information objective includes two measures under § 495.24(c)(5)(ii) and the existing Stage 3 Coordination of Care through Patient Engagement objective includes three measures under § 495.24(c)(6)(ii).

We reviewed the existing Stage 3 requirements and determined that the proposals for the Patient Electronic Access to Health Information objective and Coordination of Care through Patient Engagement objective could reduce program complexity and burden and better focus on leveraging the most current health IT functions and standards for patient flexibility of access and exchange of health information. We are proposing the Provider to Patient Exchange objective would include one measure, the existing Stage 3 Provide Patient Access measure, which are proposing to rename to Provide Patients Electronic Access to Their Health Information. In addition, we are proposing to revise the measure description for the Provide Patients Electronic Access to Their Health Information measure to change the threshold from more than 50 percent to at least one unique patient in accordance with the proposed scoring methodology proposed in section VIII.D.5. of the preamble of this proposed rule. As discussed in section VIII.D.6.a. of the preamble of this proposed rule, we are proposing to remove the exclusion for the Provide Patients Electronic Access to Their Health Information measure.

As discussed below, if we finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, we are proposing to remove all of the other measures currently associated with the Patient Electronic Access to Health Information objective and the Coordination of Care through Patient Engagement objective.

If we do not finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, we would maintain the existing Stage 3 requirements finalized in previous rulemaking as outlined in the table in that section which describes Stage 3 objectives and measures if new scoring methodology is not finalized. Therefore, we would retain the existing Patient Electronic Access to Health Information objective, associated measures and exclusions under § 495.24(c)(5) and the existing Coordination of Care through Patient Engagement objective, associated measures and exclusions under § 495.24(c)(6).

(1) Proposed Modifications To Provide Patient Access Measure

We are proposing to change the name of the Provide Patient Access measure at 42 CFR 495.24(c)(5)(ii)(A) to Provide Patients Electronic Access to Their Health Information at proposed 42 CFR 495.24(e)(7)(ii)(A) to better reflect the emphasis on patient engagement in their health care and patient's electronic access of their health information through use of APIs. We are proposing to change the measure description only to remove the previously established threshold from Stage 3, in alignment with our proposed implementation of a performance-based scoring methodology, to require that the eligible hospital or CAH provide timely access for viewing, downloading or transmitting their health information for at least one unique patient discharged using any application of the patient's choice.

Proposed name and measure description: Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

- The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and
- The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT.

We are proposing to change the measure name to emphasize electronic access of patient health information as opposed to use of paper based actions in accordance with the 2015 EHR Incentive Programs final rule policy for Stage 3 to discontinue inclusion of paper based formats and limit the focus to only health IT solutions to encourage adoption and innovation in use of CEHRT (80 FR 62783 through 62784). In addition, we are committed to promoting patient engagement with their health care information and ensuring access in an electronic format upon discharge from the eligible hospital or CAH.

We note that under the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, measures would not have required thresholds for reporting. Therefore, if the new scoring methodology and measure were finalized, this measure would not have a reporting threshold. In the event we do not finalize the proposed scoring methodology, we would maintain the existing Stage 3 requirements finalized in previous rulemaking. Therefore, eligible hospitals and CAHs would be required report on the Stage 3 Provide Patient Access measure under the Patient Electronic Access to Health Information objective codified at § 495.24(c)(5)(ii)(A).

We are inviting public comment on the measure proposal.

(2) Proposed Removal of the Patient Generated Health Data Measure

We are proposing to remove the Patient Generated Health Data (PGHD) measure at 42 CFR 495.24(c)(6)(ii)(C) at proposed § 495.24(e)(7) to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

As finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62851, the measure is not fully health IT based as we did not specify the manner in which health care providers would incorporate the data received. Instead, we finalized that health care providers could work with their EHR developers to establish the methods and processes that work best for their practice and needs. We indicated that this could include incorporation of the information using a structured format (such as an existing field in the EHR or maintaining an isolation between the data and the patient record such as incorporation as an attachment, link or text reference which would not require the advanced use of CEHRT. We note that although this measure requires use of the 2015 Edition, it does not require key updates to functions and standards of health IT, therefore, it does not align with the current program goals of improving interoperability, prioritizing actions completed electronically and use of advanced CEHRT functionalities.

We are seeking public comment on our proposal to remove the Patient Generated Health Data measure.

(3) Proposed Removal of the Patient-Specific Education Measure

We are proposing to remove the Patient-Specific Education measure at § 495.24(c)(5)(ii)(B) at proposed § 495.24(e)(7) as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from health care providers' progress on current program priorities.

The Patient-Specific Education measure was finalized as a Stage 3 measure for eligible hospitals and CAHs in the 2015 EHR Incentive Programs final rule with the intent to build upon the Stage 2 policy goals of using CEHRT for provider-patient communication (80 FR 62841 through 62846).

We believe that the Patient-Specific Education measure does not align with the current emphasis of the Medicare Promoting Interoperability Program to increase interoperability, leverage the most current health IT functions and standards or reduce burden for eligible hospitals and CAHs. For example, the Patient-Specific Education measure's primary focus is on use of CEHRT for patient resources specific to their health care and diagnosis as well as patient centered care. However, the education resources do not need to be maintained within or generated by CEHRT. Therefore, even though the CEHRT identifies the patient educational resources, the process to generate them could take additional time and interrupt health care provider's workflows. In addition, there could be redundancy in providing educational materials based on resources identified by the CEHRT as CEHRT identifies educational resources using the patient's medication list and problem list but can also include other elements as well. If there are no changes to a patient's health status or treatment based on his or her health care information, there would likely be many resources and materials that present the same type of information and could increase burden to the health care provider in seeking additional resources to provide.

We are inviting public comment on our proposal to remove the Patient-Specific Education measure.

(4) Proposed Removal of the Secure Messaging Measure

We are proposing to remove the Secure Messaging measure at § 495.24(c)(6)(ii)(B) at proposed § 495.24(e)(7) as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from health care providers' progress on current program priorities.

Secure Messaging was finalized as a Stage 3 measures for eligible hospitals and CAHs in the 2015 EHR Incentive Programs final rule with the intent to build upon the Stage 2 policy goals of using CEHRT for provider-patient communication (80 FR 62841 through 62849). As mentioned above, we believe that Secure Messaging does not align with the current emphasis of the Medicare Promoting Interoperability Program to increase interoperability or reduce burden for eligible hospitals and CAHs.

In addition, we believe there is burden associated with tracking secure messages, including the unintended consequences of workflows designed for the measure rather than for clinical and administrative effectiveness. We note that Secure Messaging is not part of the EHR Incentive Programs requirements for eligible hospitals and CAHs under Modified Stage 2. This measure was finalized in the 2015 EHR Incentive Programs final rule for Stage 3 (80 FR 62846 through 62852) under the Coordination of Care Through Patient Engagement objective which allows health care providers flexibility by requiring them to report on all three measures but only require them to meet the thresholds of two measures. This allows health care providers the option to choose measure options that best fit their organizational needs and patient population. We believe that because this measure is not currently required, removal would not negatively impact patient engagement nor care coordination and serve to decrease burden.

In addition, after further review, we believe that this measure may not be practical for eligible hospitals and CAHs as the patient would likely receive follow up care from another health care provider such as the patient's primary care physician, a rehabilitation facility, or home health after discharge. The patient would communicate with those health care providers instead of the hospital for information related to their health post-discharge.

We are inviting public comment on our proposal to remove the Secure Messaging measure.

(5) Proposed Removal of the View, Download or Transmit Measure

We are proposing to remove the View, Download or Transmit measure at § 495.24(c)(6)(ii)(A) at proposed § 495.24(e)(7) as it has proven burdensome to eligible hospitals and CAHs in ways that were unintended and detract from eligible hospitals and CAHs progress on current program priorities.

We received health care provider and stakeholder feedback through correspondence, public forums, and listening sessions indicating there is ongoing concern with measures which require patient action for successful attestation. We have noted that data analysis on the patient action measures supports stakeholder concerns that barriers exist which impact a provider's ability to meet them. Health care providers have noted that the demographics of their patient populations which may include low-income, location in remote, rural areas and an aging population contribute to the barriers as the patients do not have access to computers, internet and/or email. They have also noted that this particular population is concerned with having their health information online. In addition, stakeholders have indicated that successful attestation of the measure is reliant upon the patient, and patient education and engagement may not be enough to overcome the barriers. In the 2015 EHR Incentive Programs final rule at 80 FR 62789, we reduced the thresholds for both patient action measures of VDT and Secure Messaging based on concerns from health care providers and to increase successful attestation on this measure. After additional review, we note that successful attestation predicated solely on a patient's action has inadvertently created burdens to health care providers and detracts from progress on the Promoting Interoperability Program's measure goals of focusing on patient care, interoperability and leveraging advanced used of health IT. Therefore, we are proposing to remove the View, Download or Transmit measure.

We are inviting public comment on our proposal to remove the View, Download or Transmit measure.

e. Proposed Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures

In connection with the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, we are proposing changes to the Public Health and Clinical Data Registry Reporting objective and six associated measures under 42 CFR 495.24(c)(8)(ii)(A) through (F) in proposed 42 CFR 495.24(e)(7). We believe that public health reporting through EHRs will extend the use of electronic reporting solutions to additional events and care processes, increase timeliness and efficiency of reporting and replace manual data entry.

We are proposing to change the name of the objective to Public Health and Clinical Data Exchange. Under the new scoring methodology proposed in section VII.D.5. of the preamble of this proposed rule, in aligning with our goal to increase flexibility, improve value, and focus on burden reduction, we are proposing that eligible hospitals and CAHs would be required to attest to the Syndromic Surveillance Reporting measure and at least one additional measure from the following options: Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting.

We are proposing to require the Syndromic Surveillance Reporting measure under the Public Health and Clinical Data Exchange objective because the CDC indicates the primary source of data for syndromic surveillance comes from EHRs in emergency care settings. Typically, EHR data transmitted from health care facilities to public health agencies for syndromic surveillance are not filtered or categorized. As a result, public health agencies can use the same data that support delivery of care for an all-hazards surveillance approach.

The EHR Incentive Program has enabled the growth of syndromic surveillance across the country and in a number of States, such as Illinois and Wisconsin, nearly all of the hospitals with emergency departments are participating. More complete coverage allows public health agencies to monitor trends in emergency department visits with more precision, detect smaller increases in morbidity, identify emerging health threats in smaller geographic areas, and collaborate with healthcare and other State agencies to respond quickly to emerging health threats.

In addition, syndromic surveillance reporting via CEHRT leverages the wealth and depth of clinical information that has not been captured before to study emerging health conditions like the rising opioid overdose epidemic. The data will also provide a unique opportunity to examine rare conditions and new procedures. We are seeking public comment on the proposal to require reporting on this measure.

We stated in the 2015 EHR Incentive Programs final rule at 80 FR 62771 that one of the program goals was to increase interoperability through public health registry exchange of data. We continue to believe that public health reporting is valuable in terms of health information exchange between health care providers and public health and clinical data registries. For example, when immunization information is directly exchanged between EHRs and registries, patient information may be accessed by all of a patient's health care providers for improved continuity of care and reduced provider burden, as well as supporting population health monitoring. While we believe that it is important to leverage health IT through advanced use of CEHRT, for public health and clinical data registries reporting, we also want to reduce burden. Through stakeholder feedback, we understand that some of the existing active engagement requirements are

complicated and confusing, and contributed to unintended burden due to issues related to readiness or onboarding for electronic exchange with registries. Therefore, under the new scoring methodology proposed in section VII.D.5. of the preamble of this proposed rule, we are proposing to require attestation to only two measures under the Public Health and Clinical Data Exchange objective instead of three, which is currently required under Stage 3.

In addition, we intend to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022, and are seeking public comment on whether hospitals will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective and measures are removed, as well as other policy levers outside of the Promoting Interoperability Program that could be adopted for continued reporting to public health and clinical data registries, if necessary. As noted above, while we believe that these registries provide the necessary monitoring of public health nationally and contribute to the overall health of the nation, we are also focusing on reducing burden and identifying other appropriate venues in which reporting to public health and clinical data registries could be reported. We are seeking public comment on the role that each of the public health and clinical data registries should have in the future of the Promoting Interoperability Programs and whether the submission of this data should still be required when the incentive payments for meaningful use of CEHRT will end in 2021.

Lastly, we are seeking public comment on whether the Promoting Interoperability Programs are the best means for promoting the sharing of clinical data with public health entities.

In the event we do not finalize the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule, we would maintain the existing Stage 3 requirements finalized in previous rulemaking and outlined in the table in that section which describes Stage 3 objectives and measures if new scoring methodology is not finalized. Therefore, we would retain the existing Public Health and Clinical Data Registry Reporting objective and associated measures and exclusions under § 495.24(c)(8).

f. Request for Comment—Potential New Measures for HIE Objective: Health Information Exchange Across the Care Continuum

We are working to introduce additional flexibility to allow providers a wider range of options in selecting measures that are most appropriate to their setting, patient population, and clinical practice improvement goals. For this reason, we are seeking public comment on a potential concept for two additional measure options for the Health Information Exchange objective for eligible hospitals and CAHs.

The Stage 3 program requirements for health information exchange primarily focused on the exchange between and among eligible hospitals, CAHs and eligible professionals. While these use cases represent a significant portion of the health care industry, the care continuum is much broader and includes a wide range of health care providers and settings of care that have adopted and implemented health IT systems to support patient care and electronic information exchange. Specifically, health care providers in long-term care and post-acute care settings, skilled nursing facilities, and behavioral health settings have made significant advancements in the adoption and use of health IT. Many current Promoting Interoperability Program participants are now engaged in bi-directional exchange of patient health information with these health care providers and settings of care and many more are seeking to incorporate these workflows as part of efforts to improve care team coordination or to support alternative payment models.

For these reasons, we are seeking public comment on two potential new measures for inclusion in the program to enable eligible hospitals and CAHs to exchange health information through health IT supported care coordination across a wide range of settings.

New Measure Description for Support Electronic Referral Loops by Sending Health Information Across the Care Continuum: For at least one transition of care or referral to a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH creates a summary of care record using CEHRT; and electronically exchanges the summary of care record.

New Measure Denominator: Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transitioning or referring provider to a provider of care other than an eligible hospital or CAH.

New Measure Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created and exchanged electronically using CEHRT.

New Measure Description for Support Electronic Referral Loops By Receiving and Incorporating Health Information Across the Care Continuum: For at least one electronic summary of care record received by an eligible hospital or CAH from a transition of care or referral from a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH conducts clinical information reconciliation for medications, mediation allergies, and problem list.

New Measure Denominator: The number of electronic summary of care records received for a patient encounter during the EHR reporting period for which an eligible hospital or CAH was the recipient of a transition of care or referral from a provider of care other than an eligible hospital or CAH.

New Measure Numerator: The number of electronic summary of care records in the denominator for which clinical information reconciliation was completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.

We are seeking public comment on whether these two measures should be combined into one measure so that an eligible hospital or CAH that is engaged in exchanging health information across the care continuum may include any such exchange in a single measure. We are seeking public comment on whether the denominators should be combined to a single measure including both transitions of care from a hospital and transitions of care to a hospital. We also are seeking public comment on whether the numerators should be combined to a single measure including both the sending and receiving of electronic patient health information. We are seeking public comment on whether the potential new measures should be considered for inclusion in a future program year or whether stakeholders believe there is sufficient readiness and interest in these measures to adopt them as early as 2019. For the purposes of focusing the denominator, we are seeking public comment regarding whether the potential new measures should be limited to transitions of care and referrals specific to long-term and post-acute care, skilled nursing care,

and behavioral health care settings. We also are seeking public comment on whether additional settings of care should be considered for inclusion in the denominators and if a provider should be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model. Finally, we are seeking public comment on the impact the potential new measures may have for health IT developers to develop, test, and implement a new measure calculation for a future program year.

7. Proposed Application of Proposed Scoring Methodology and Measures Under the Medicaid Promoting Interoperability Program

As indicated in sections VIII.D.5. and VIII.D.6. of the preamble of this proposed rule, we are not proposing to require States to adopt the new scoring methodology and measures that we are proposing. Instead, we are proposing to give States the option to adopt the new scoring methodology we are proposing in section VIII.D.5. of the preamble of this proposed rule together with the measures proposals included in section VIII.D.6. of the preamble of this proposed rule for their Medicaid Promoting Interoperability Programs. Any State that wishes to exercise this option must submit a change to its State Medicaid HIT Plan (SMHP) for CMS' approval, as specified in § 495.332. If a State chooses not to submit such a change, or if the change is not approved, the objectives, measures, and scoring would remain the same as currently specified under § 495.24. We believe that States are unlikely to choose this option due to concerns with burden, time constraints and costs associated with implementing updates to technology and reporting systems, as very few eligible hospitals will be eligible to receive an incentive payment under the Medicaid Promoting Interoperability Program in 2019 and subsequent years. However, our proposal to extend this option to States would allow them flexibility to benefit from the improvements to meaningful use scoring outlined in this proposed rule, if they so choose. Similarly, we also request public comment on whether we should modify the objectives and measures for eligible professionals (EPs) in the Medicaid Promoting Interoperability Program in order to encourage greater interoperability for Medicaid EPs. We are interested in policy options that should be considered, including the benefits of greater alignment with the Merit-Based Incentive Payment System requirements for Eligible Clinicians. We also are inviting comments on the burdens and hurdles that such policy changes might create for EPs and States.

In connection with these proposals regarding the scoring methodology and measures, we are proposing to require under § 495.40(b)(2)(vii) ''dual-eligible'' eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use, and are also eligible to earn a Medicaid incentive payment for meaningful use) to demonstrate meaningful use for the Promoting Interoperability Program to CMS, and not to their respective State Medicaid agency, beginning with the EHR reporting period in CY 2019. This includes all attestation requirements, including the objectives and measures of meaningful use, in addition to reporting clinical quality measures. In the past, we have generally adopted a common definition of meaningful use under Medicare and Medicaid (for example, 77 FR 44324 through 44326). If we adopt the proposals made in this rule, there would not be a common definition of meaningful use, unless a State chooses to exercise the option described above and receives approval from CMS. In light of these changes, we believe it would be more efficient and straightforward in terms of program administration and operations if all dual-eligible eligible hospitals and CAHs demonstrate meaningful use to CMS. If a dual-eligible eligible hospital or CAH instead demonstrates meaningful use to its State Medicaid agency, it would only qualify for an incentive payment under Medicaid (assuming it meets all eligibility and other program requirements), and it would not qualify for an incentive payment under Medicare and/or avoid the Medicare payment reduction. The proposals in this rule would not change the deeming policy under the definition of meaningful EHR user under § 495.4, under which an eligible hospital or CAH that successfully demonstrates meaningful use to CMS would be deemed a meaningful EHR user for purposes of the Medicaid incentive payment.

We also are proposing to amend the requirements for State reporting to CMS under the Medicaid Promoting Interoperability Program under § 495.316(g), so that States would not be required to report, for program years after 2018, provider-level attestation data for each eligible hospital that attests to the State to demonstrate meaningful use.

We are seeking public comments on these proposals.

8. Promoting Interoperability Program Future Direction

In future years of the Promoting Interoperability Program, we will continue to consider changes which support a variety of HHS goals, including: Reducing administrative burden, supporting alignment with the Quality Payment Program, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. We believe a focus on interoperability and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery. One strategy we are exploring is creating a set of priority health IT activities that would serve as alternatives to the traditional EHR Incentive Program measures.

For example, we are seeking public comment on whether participation in the Trusted Exchange Framework and Common Agreement (TEFCA) should be considered a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. The 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, requires HHS to take steps to enable the electronic sharing of health information ensuring interoperability for health care providers and settings across the care continuum. Congress directed ONC to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' In January 2018, ONC released a draft version of the Trusted Exchange Framework.[383] ONC will revise the draft TEF based on public comment and ultimately release a final version of the Trusted Exchange Framework that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. By participating in, or serving as, a health information network, health IT developers and other stakeholders can ensure that health care providers have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and

[383] The draft version of the Trusted Exchange Framework may be accessed at: *https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

applicable privacy and security requirements.

To qualify for this activity, an eligible hospital or CAH would demonstrate that they are using CEHRT from a developer who participates in or serves as a health information network which has adopted the TEFCA. Eligible hospitals and CAHs could also be required to demonstrate that they are active participants in a health information network and routinely sharing health information to support care transitions. They could also be required to demonstrate that their CEHRT enables the use of an open API to exchange information with the network.

We also are considering a health IT activity in which eligible hospitals and CAHs could obtain credit if they maintain an open API which allows patients to access their health information through a preferred third party. This could be the open API maintained to comply with the terms of the TEFCA or a standalone offering as long as the API offers ongoing persistent access to outside parties. Under this approach, an eligible hospital or CAH that attests to making such an open API available for the purposes of ensuring patients have access to their health information would receive full credit for the Provide Patient Access measure under this objective.

Finally, we are considering developing a health IT activity which would allow eligible hospitals and CAHs to obtain credit under the Public Health and Clinical Data Exchange objective for piloting emerging technology standards. A priority outcome for the draft Trusted Exchange Framework is enabling bulk data queries which health care providers and other stakeholders can utilize to conduct effective population health management across their entire attributed population. However, technical infrastructure to support this use case on a widespread basis is still in development.

HHS could develop a health IT activity under which an eligible hospital or CAH would participate in a pilot, and eventually implement in production, use of an API based on the emerging update to the FHIR standard which would allow population level data access through an API in lieu of reporting on measures under the Public Health and Clinical Data Exchange objective.

We welcome stakeholder comments on the concept of adopting health IT activities, and specifically on the health IT activities described above. We also welcome recommendations for other health IT activities through which eligible hospitals and CAHs could earn credit in lieu of reporting on specific measures, and which add value for patients and health care providers, are relevant to patient care and clinical workflows, support alignment with existing objectives, promote flexibility, are feasible for implementation, are innovative in the use of health IT and promote interoperability.

Finally, we specifically are seeking public comments on the following questions:

- What health IT activities should CMS consider recognizing in lieu of reporting on objectives that would most effectively advance priorities for nationwide interoperability and spur innovation? What principles should CMS employ to identify health IT activities?
- Do stakeholders believe that introducing health IT activities in lieu of reporting on measures would decrease burden associated with the Promoting Interoperability Programs?
- If additional measures were added to the program, what measures would be beneficial to add to promote our goals of care coordination and interoperability?
- How can the Promoting Interoperability Program for eligible hospitals and CAHs further align with the Quality Payment Program (for example, requirements for eligible clinicians under MIPS and Advanced APMs) to reduce burden for health care providers, especially hospital-based MIPS eligible clinicians?
- What other steps can HHS take to further reduce the administrative burden associated with the Promoting Interoperability Program?

9. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the Medicare and Medicaid Promoting Interoperability Programs

a. Background and Current CQMs

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 (referred to as CQMs or eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid Promoting Interoperability Programs.

The table below lists the 16 CQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid PI Programs beginning in CY 2017 (81 FR 57255).

CQMs for Eligible Hospitals and CAHs Beginning With CY 2017

Short name	Measure name	NQF No.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
ED–3	Median Time from ED Arrival to ED Departure for Discharged ED Patients	0496
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01	Elective Delivery (Collected in aggregate, submitted via web-based tool or electronic clinical quality measure).	0469
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
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

+ NQF endorsement has been removed.

* Measure name has been shortened. We refer readers to annually updated measure specifications on the CMS eCQI Resource Center web page for further information at: *https://www.healthit.gov/newsroom/ecqi-resource-center*.

b. Proposed CQMs for Reporting Periods Beginning With CY 2020

As we have stated previously in rulemaking (82 FR 38479), we plan to continue to align the CQM reporting requirements for the PI Programs with the Hospital IQR Program. In order to move the program forward in the least burdensome manner possible, while maintaining a set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients, we believe it is appropriate to propose to remove certain eCQMs at this time to develop an even more streamlined set of the most meaningful eCQMs for hospitals. To align with the Hospital IQR Program, we are proposing to reduce the number of eCQMs in the Medicare and Medicaid Promoting Interoperability Programs eCQM measure set from which eligible hospitals and CAHs report, by proposing to remove eight eCQMs (from the 16 eCQMs currently in the measure set) beginning with the reporting period in CY 2020. The eight eCQMs we are proposing to remove are:

- Primary PCI Received Within 90 Minutes of Hospital Arrival (NQF #0163) (AMI–8a);
- Home Management Plan of Care Document Given to Patient/Caregiver (CAC–3);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED–1);
- Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI–1a);
- Elective Delivery (NQF #0469) (PC–01);
- Stroke Education (STK–08) (adopted at 78 FR 50807;
- Assessed for Rehabilitation (NQF #0441) (STK–10); and
- Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF 0496) (ED–3).

We note that the first seven eCQMs on this list are currently included in the Hospital IQR Program, and in section VIII.A.5.(b)(9), we are proposing to remove them from the Hospital IQR Program beginning in CY 2020. For more information on the first seven eCQMs selected for removal, we refer readers to section VIII.A.5.(b)(9) of the preamble of this proposed rule.

We believe that a coordinated reduction in the overall number of eCQMs in both the Hospital IQR Program and Medicare and Medicaid EHR Promoting Interoperability will reduce certification burden on hospitals, improve the quality of reported data by enabling eligible hospitals and CAHs to focus on a smaller, more specific subset of CQMs while still allowing eligible hospitals and CAHs some flexibility to select which eCQMs to report that best reflect their patient populations and support internal quality improvement efforts. With respect to the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (NQF 0496) (ED–3), this is an outpatient measure and is not included as an eCQM in the Hospital IQR Program. We are proposing to remove it so the eCQMs would align completely between the two programs in order to reduce burden and enable eligible hospitals and CAHs to easily report electronically through the Hospital IQR Program submission mechanism.

As we stated in section VIII.A.5.(b)(9) with regard to the Hospital IQR Program proposal for the CY 2020 reporting period and subsequent years, we also considered proposing to remove these eCQMs one year earlier, beginning with the CY 2019 reporting period/FY 2021 payment determination. In establishing our eCQM policies, we must balance the needs of eligible hospitals and CAHs with variable preferences and capabilities. Overall, across the range of capabilities and resources for eCQM reporting, stakeholders have expressed that they want more time to prepare for eCQM changes.

We recognize that some hospitals and health IT vendors may prefer earlier removal in order to forgo maintenance on those eCQMs proposed for removal. In preparation for this proposed rule, we weighed the relative burdens associated with removing these measures beginning with the CY 2019 reporting period or beginning with the CY 2020 reporting period. In the event we finalize our proposal to remove these eCQMs, we intend to align the timing of the removal for the Medicare and Medicaid Promoting Interoperability Programs with the Hospital IQR Program.

We are inviting public comment on our proposal, including the specific measures proposed for removal and the timing of removal from the Medicare and Medicaid Promoting Interoperability Programs.

d. Proposed CQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019

For CY 2019, we are proposing the same CQM reporting periods and criteria as established in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479 through 38483) for the Medicare and Medicaid EHR Incentive Programs in CY 2018, which would be as follows:

For CY 2019, for eligible hospitals and CAHs that report CQMs electronically, we are proposing the reporting period for the Medicare and Medicaid Promoting Interoperability Programs would be one, self-selected calendar quarter of CY 2019 data, and the submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the calendar year, ending February 29, 2020. For eligible hospitals and CAHs that report CQMs by attestation under the Medicare Promoting Interoperability Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid Promoting Interoperability Program, we previously established a CQM reporting period of the full CY 2019 (consisting of 4 quarterly data reporting periods) (80 FR 62893). We also established an exception to this full-year reporting period for eligible hospitals and CAHs demonstrating meaningful use for the first time under their State's Medicaid EHR Incentive Program. Under this exception, the CQM reporting period is any continuous 90-day period within CY 2019 (80 FR 62893). We are proposing that the submission period for eligible hospitals and CAHs reporting CQMs by attestation under the Medicare EHR Incentive Program would be the 2 months following the close of the CY 2019 CQM reporting period, ending February 29, 2020. In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the method of reporting CQMs (attestation or electronic reporting) and the submission periods for reporting CQMs, subject to prior approval by CMS.

For the CY 2019 reporting period, we are proposing that the reporting criteria under the Medicare and Medicaid Promoting Interoperability Program for eligible hospitals and CAHs reporting CQMs electronically would be as follows: For eligible hospitals and CAHs participating only in the Promoting

Interoperability Program, or participating in both the Promoting Interoperability Program and the Hospital IQR Program, report on at least 4 self-selected CQMs from the set of 16 available CQMs listed in the table above.

We are proposing the following reporting criteria for eligible hospitals and CAHs that report CQMs by attestation under the Medicare Promoting Interoperability Program as a result of electronic reporting not being feasible, and for eligible hospitals and CAHs that report CQMs by attestation under their State's Medicaid Promoting Interoperability Program, for the reporting period in CY 2019—report on all 16 available CQMs listed in the table in section VIII.D.9.a. of the preamble of this proposed rule, above.

We are requesting public comments on these proposals.

e. CQM Reporting Form and Method for the Medicare Promoting Interoperability Program in CY 2019

As we stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760), for the reporting periods in 2016 and future years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive (now Promoting Interoperability) Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49760), States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

The form and method of electronic submission are further explained in sub-regulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center web page at: *https://ecqi.healthit.gov/*. For further information on CQM reporting, we refer readers to the EHR Incentive Program (now Promoting Interoperability Program) website where guides and tip sheets are located at: *http://www.cms.gov/ehrincentiveprograms*. For the reporting period in CY 2019 reporting period, we are proposing the following for CQM submission under the Medicare Promoting Interoperability Program:

- Eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (single program participation)—electronically report CQMs through QualityNet Portal.
- Eligible hospital and CAH options for electronic reporting for multiple programs (that is, Promoting Interoperability Program and Hospital IQR Program participation)—electronically report through QualityNet Portal.

As noted in the 2015 EHR Incentive Programs final rule (80 FR 62894), starting in 2018, eligible hospitals and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible. For the Medicaid Promoting Interoperability Program, States continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

For CY 2019, we are proposing to continue our policy regarding the electronic submission of CQMs, which requires the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. For the CY 2019 electronic reporting of CQMs, this means eligible hospitals and CAHs are required to use the Spring 2017 version of the CQM electronic specifications and any applicable addenda available on the eCQI Resource Center web page at: *https://ecqi.healthit.gov/*. In addition, we are proposing that eligible hospitals or CAHs must have their EHR technology certified to all 16 available CQMs listed in the table above. As discussed in section VIII.D.3. of the preamble of this proposed rule, eligible hospitals and CAHs are required to use 2015 Edition CEHRT for the Medicare and Medicaid Promoting Interoperability Programs in CY 2019. We reiterate that an EHR certified for CQMs under the 2015 Edition certification criteria does not have to be recertified each time it is updated to a more recent version of the CQMs (82 FR 38485).

We are requesting public comments on these proposals.

f. Request for Comment

Stakeholders continue to identify areas for improvement in the implementation of eCQMs under a variety of CMS programs, including the Hospital IQR Program and the Medicare and Medicaid EHR Incentive (now Promoting Interoperability) Programs. While effective utilization of eCQMs promises greater efficiency and more timely access to data to support quality improvement activities, various types of burden associated with these measurement approaches detracts from these benefits. Moreover, some providers may have low awareness of the resources and tools available to help address issues that arise in utilizing eCQMs.

Program design and operations associated with measurement aspects of these programs can be a significant source of burden for providers. Uncertainty around rapidly shifting timelines and requirements can pose significant financial and operational planning challenges for organizations, while lack of alignment across programs results in further complexity. In addition, the implementation of eCQMs within the EHR is a significant source of burden. Health IT products vary widely in the eCQMs they offer, and incorporating new measure specifications into a product, along with validation and testing of the updates, can be challenging and time-consuming. Lack of transparency from developers around data sources within the EHR, mapping, measure calculations, and reporting schemas, can hinder providers' ability to implement eCQMs and ensure the accuracy of results. Moreover, challenges in extracting data from the EHR and integrating with other applications can serve as a source of burden for providers seeking to bring together different technology solutions and work with other third party services to complete reporting and quality improvement activities.

Stakeholders have expressed support for increasing the availability of new eCQMs, developing eCQMs that focus on patient outcomes and higher impact measurement areas, and exploring how eCQMs can reduce the burden associated with chart-abstracted measures. However, they have also identified barriers which may contribute to a lack of adequate development of eCQMs and limit their potential, including long development timelines, lack of guidelines/prioritization of and participation in eCQM development, limited field testing, and program policies that limit innovation by focusing on ''least common denominator'' approaches.

We are seeking stakeholder feedback on ways that we could address these and other challenges related to eCQM use. Specifically, we are inviting comment on the following:

• What aspects of the use of eCQMs are most burdensome to hospitals and health IT vendors?
• What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM burden?
• What are the most significant barriers to the availability and use of new eCQMs today?
• What specifically would stakeholders like to see us do to reduce burden and maximize the benefits of eCQMs?
• How could we encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?
• How could we encourage hospitals and health IT vendors to engage in testing new eCQMs?
• Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?
• What ways could we incentivize or reward innovative uses of health IT that could reduce burden for hospitals?
• What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

10. Participation in the Medicare Promoting Interoperability Program for Subsection (d) Puerto Rico Hospitals

a. Background

In the Stage 1 final rule (77 FR 44448), we noted that subsection (d) Puerto Rico hospitals as defined in section 1886(d)(9)(A) of the Act were not ''eligible hospitals'' as defined in section 1886(n)(6)(B) of the Act, and therefore were not eligible for the incentive payments for the meaningful use of CEHRT under section 1886(n) of the Act. Section 602(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) subsequently amended section 1886(n)(6)(B) of the Act to include subsection (d) Puerto Rico hospitals in the definition of ''eligible hospital,'' which made subsection (d) Puerto Rico hospitals eligible for the incentive payments under section 1886(n) of the Act for hospitals that are meaningful EHR users and subject to the payment reductions under section 1886(b)(3)(B)(ix) of the Act for hospitals that are not meaningful EHR users. In order to take into account delays in implementation, section 602(d) of the Consolidated Appropriations Act, 2016 adjusted the existing timelines for the incentive payments by five years and payment reductions by 7 years for subsection (d) Puerto Rico hospitals, as further discussed in the sections below.

As authorized under section 602(c) of the Consolidated Appropriations Act, 2016, we have previously elected to implement the amendments made by section 602 as applied to subsection (d) Puerto Rico hospitals through program instruction. In doing so we have sought to align the policies for subsection (d) Puerto Rico hospitals with our existing policies for eligible hospitals under the Medicare Promoting Interoperability Program to the greatest extent possible, while taking into account the unique circumstances applicable to hospitals on Puerto Rico. In the following sections of the proposed rule, we are proposing to codify the program instructions we have issued to subsection (d) Puerto Rico hospitals and to amend our regulations under Parts 412 and 495 such that the provisions that apply to eligible hospitals would include subsection (d) Puerto Rico hospitals unless otherwise indicated.

We are requesting public comments on the proposals made in the following sections.

b. Definitions

(1) Eligible Hospital: Subsection (d) Puerto Rico Hospitals

We are proposing to define a ''Puerto Rico eligible hospital'' under § 495.100 as a subsection (d) Puerto Rico hospital as defined in section 1886(d)(9)(A) of the Act.

We are proposing to amend the definition of ''eligible hospital'' under § 495.100 to include Puerto Rico eligible hospitals unless otherwise indicated.

We are proposing to amend the general provisions under § 412.200 as related to prospective payment rates for inpatient operating costs for subsection (d) Puerto Rico hospitals.

(2) EHR Reporting Period: Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that for subsection (d) Puerto Rico hospitals, FY 2016 is the first payment year under section 1886(n)(2)(G)(i) of the Act for which an incentive payment could be made to a hospital that is a meaningful EHR user. The definition of ''EHR reporting period'' under § 495.4 specifies for eligible hospitals for the FY 2016 payment year an EHR reporting period of any continuous 90-day period in CY 2016, which is consistent with the program instructions we issued to subsection (d) Puerto Rico hospitals, so we do not believe any amendment is necessary. We are proposing to amend the definition of ''EHR reporting period'' under § 495.4 to specify for Puerto Rico eligible hospitals for the FY 2017 payment year an EHR reporting period of a minimum of any continuous 14-day period in CY 2017, which is consistent with the program instructions we issued to subsection (d) Puerto Rico hospitals. We allowed for a 14-day EHR reporting period in CY 2017 to acknowledge and account for the devastation to Puerto Rico caused by Hurricane Maria. We have not issued program instructions to subsection (d) Puerto Rico hospitals concerning the EHR reporting periods for the payment years after FY 2017. For the FY 2018, 2019, and 2020 payment years, we are proposing an EHR reporting period of a minimum of any continuous 90-day period in CYs 2018, 2019, and 2020 respectively for Puerto Rico eligible hospitals, and we are proposing corresponding amendments to the definition of ''EHR reporting period'' under § 495.4.

(3) EHR Reporting Period for a Payment Adjustment Year for Eligible Hospitals: Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that the payment reductions under section 1886(b)(3)(B)(ix) of the Act would apply beginning with FY 2022 for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for the applicable EHR reporting period for the payment adjustment year. Because Puerto Rico eligible hospitals would be considered eligible hospitals, the EHR reporting periods for payment adjustment years and related policies, including deadlines and requests for significant hardship exceptions, that we establish for eligible hospitals would also apply to Puerto Rico eligible hospitals beginning with the FY 2022 payment adjustment year.

(4) Payment Year for Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that for subsection (d) Puerto Rico hospitals, FY 2016 is the first payment year under section 1886(n)(2)(G)(i) of the Act for which an incentive payment could be made to a hospital that is a meaningful EHR user. We are proposing to amend the definition of ''payment year'' under § 495.4 to specify for Puerto Rico eligible hospitals, payment year means a Federal FY beginning with 2016.

(5) Payment Adjustment Year for Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that the payment reductions under section 1886(b)(3)(B)(ix) of the Act will apply beginning with FY 2022 for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for the applicable EHR reporting period for the payment adjustment year. We are proposing to amend the definition of ''payment adjustment year'' under § 495.4 to specify for Puerto Rico eligible hospitals, payment adjustment year means a Federal fiscal year beginning with 2022.

c. Duration and Timing of Incentive Payments for Subsection (d) Puerto Rico Hospitals—Transition Periods and Transition Factors

Section 602(d) of the Consolidated Appropriations Act, 2016 provides for a phase down under section 1886(n)(2)(E)(ii) of the Act for subsection (d) Puerto Rico hospitals whose first payment year is after 2018. We are proposing to amend § 495.104(b) to specify the following years for which Puerto Rico eligible hospitals may receive incentive payments under section 1886(n) of the Act:

- Puerto Rico eligible hospitals whose first payment year is FY 2016 may receive such payments for FYs 2016 through 2019.
- Puerto Rico eligible hospitals whose first payment year is FY 2017 may receive such payments for FYs 2017 through 2020.
- Puerto Rico eligible hospitals whose first payment year is FY 2018 may receive such payments for FYs 2018 through 2021.
- Puerto Rico eligible hospitals whose first payment year is FY 2019 may receive such payments for FY 2019 through 2021.
- Puerto Rico eligible hospitals whose first payment year is FY 2020 may receive such payments for FY 2020 through 2021.

We are proposing to amend § 495.104(c)(5) to specify the following transition factors under section 1886(n)(2)(E)(i) of the Act for Puerto Rico eligible hospitals:

PROPOSED TRANSITION FACTORS FOR SUBSECTION (d) PUERTO RICO HOSPITALS

	First Payment Year (FY)				
	2016	2017	2018	2019	2020
2016	1.00				
2017	0.75	1.00			
2018	0.50	0.75	1.00		
2019	0.25	0.50	0.75	0.75	
2020	.....	0.25	0.50	0.50	0.50
2021	.....	.....	0.25	0.25	0.25

d. Market Basket Adjustment for Subsection (d) Puerto Rico Hospitals

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that the payment reductions under section 1886(b)(3)(B)(ix) of the Act would apply beginning with FY 2022 for subsection (d) Puerto Rico hospitals. We are proposing for a subsection (d) Puerto Rico hospital that is not a meaningful EHR user for the EHR reporting period for the FY, three-quarters of the applicable percentage increase otherwise applicable for such FY shall be reduced by 33 1/3 percent for FY 2022, 66 2/3 percent for FY 2023, and 100 percent for FY 2024 and each subsequent FY. We are proposing to amend § 412.64(d)(3) to reflect these proposed reductions.

11. Proposed Modifications to the Medicare Advantage Promoting Interoperability Program

a. Participation in the Medicare Advantage Promoting Interoperability Program for Subsection (d) Puerto Rico Hospitals

Section 1853(m) of the Act provides for incentive payments to qualifying Medicare Advantage (MA) organizations for certain affiliated eligible hospitals (as defined in section 1886(n)(6)(B)) that meaningfully use certified EHR technology, and for application of downward payment adjustments to qualifying MA organizations for their affiliated hospitals that are not meaningful users of certified EHR technology, beginning in FY 2015. As noted in section D.8 of this proposed rule, section 602(a) of the Consolidated Appropriations Act, 2016 amended section 1886(n)(6)(B) of the Act to include subsection (d) Puerto Rico hospitals in the definition of ''eligible hospital.'' We note that the definition of ''qualifying MA-affiliated hospital'' in § 495.200 means an eligible hospital under section 1866(n)(6) that meets certain other criteria. Therefore, the amendment to section 1866(n)(6) by the Consolidated Appropriations Act to include subsection (d) Puerto Rico hospitals renders such hospitals potentially eligible as qualifying MA-affiliated hospitals for purposes of the Medicare Advantage EHR/PI incentives and payment adjustments. We are proposing certain changes to our regulations under 42 CFR part 495 so that the incentive payment and payment adjustment provisions that apply to MA-affiliated eligible hospitals are applicable to MA-affiliated eligible hospitals in Puerto Rico.

b. Definitions

(1) Payment Year for MA-Affiliated Eligible Hospitals in Puerto Rico

Section 602(d) of the Consolidated Appropriations Act, 2016 provides that for subsection (d) Puerto Rico hospitals, FY 2016 is the first payment year for which an EHR incentive payment could be made to an eligible hospital that is a meaningful EHR user. We are proposing to amend the definition of ''payment year'' under § 495.200 to specify that, with respect to MA-affiliated eligible hospitals in Puerto Rico, payment year means a Federal FY beginning with 2016.

(2) MA Payment Adjustment Year for MA-Affiliated Eligible Hospitals in Puerto Rico

Section 602(d) of the Consolidated Appropriations Act, 2016 provides for payment reductions to subsection (d) Puerto Rico hospitals that are not meaningful EHR users for the applicable EHR reporting period for the payment adjustment year, beginning with FY 2022. We are proposing to amend the definition of ''MA payment adjustment year'' under § 495.200 to specify that, for qualifying MA organizations that first receive an MA EHR incentive payment for at least 1 payment year for

an MA-affiliated eligible hospital in Puerto Rico, payment adjustment year means a calendar year starting with 2022.

We are soliciting feedback on whether we should amend the definition of ''MA payment adjustment year'' to specify that the duration of the reporting period for MA-affiliated eligible hospitals for purposes of determining whether a qualifying MA organization is subject to a payment adjustment should be other than the full federal fiscal year ending in the MA payment adjustment year. We also are requesting comments on an alternative approach under which we would use the same reporting period that is used for the Medicare Promoting Interoperability Program.

c. Payment Adjustments Effective for 2015 and Subsequent MA Payment Years With Respect to MA-Affiliated Eligible Hospitals

Under § 495.211, beginning for MA payment adjustment year 2015, payment adjustments set are made to prospective payments (issued under section 1853(a)(1)(A) of the Act) of qualifying MA organizations that previously received incentive payments under the MA EHR Incentive (now Promoting Interoperability) Program, if all or a portion of the MA-affiliated eligible hospitals that would meet the definition of qualifying MA-affiliated eligible hospitals (but for their demonstration of meaningful use) are not meaningful EHR users. Section 495.211(e) sets forth the formula for calculating payment adjustments for 2015 and subsequent years with respect to MA-affiliated eligible hospitals. We are proposing to amend paragraph (e) by adding a new subparagraph (4), which specifies that, prior to payment adjustment year 2022, subsection (d) Puerto Rico hospitals are neither qualifying nor potentially qualifying MA-affiliated eligible hospitals for purposes of applying the payment adjustments under § 495.211.

We are soliciting comment on whether further regulatory amendments are necessary or appropriate so that the EHR incentive payment and payment adjustment provisions that apply to MA-affiliated eligible hospitals are applicable to MA-affiliated eligible hospitals in Puerto Rico in a manner that is consistent with the Consolidated Appropriations Act, 2016.

12. Proposed Modifications to the Medicaid Promoting Interoperability Program

The policies proposed in this section would apply only in the Medicaid EHR Incentive (now Promoting Interoperability) Program.

a. Proposed Requirements Regarding Prior Approval of Requests for Proposals (RFPs) and Contracts in Support of the Medicaid Promoting Interoperability Program

Section 1903(a)(3)(F)(ii) of the Act establishes an enhanced federal matching rate of 90 percent for State expenditures related to the administration of Medicaid Promoting Interoperability Program payments. On July 28, 2010, in the Stage 1 final rule (75 FR 44313, 44507), we established prior approval requirements for State funding, planning documents, proposed budgets, project schedules, and certain implementation activities that a State may wish to pursue in support of the Medicaid Promoting Interoperability Program, as a condition of receipt of the 90 percent FFP available to States under section 1903(a)(3)(F)(ii) of the Act. To minimize the burden on States, we designed the prior approval conditions and prior approval process to mirror what was at the time used in support of acquiring automated data processing (ADP) equipment and services in conjunction with development and operation of States' Medicaid Management Information Systems (MMIS), which are the States' automated mechanized claims processing and information retrieval systems approved by CMS. Specifically, at § 495.324(b)(2) we established that, as a condition of receiving 90 percent FFP for administration of their Medicaid Promoting Interoperability programs, States must receive prior approval for requests for proposals and contracts used to complete activities under 42 CFR part 495 subpart D, unless specifically exempted by HHS, before release of the request for proposal or execution of the contract. This was consistent with the requirement then in place for MMIS at 45 CFR 95.611(a)(2). At section 495.324(b)(3) we established that unless specifically exempted by HHS, States must receive prior approval for contract amendments involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days, prior to execution of the contract amendment. This was consistent with the requirement then in place at 45 CFR 95.611(b)(2)(iv).

Subsequently, in the final rule titled ''State Systems Advance Planning Document (APD) Process'' (75 FR 66319, October 28, 2010), HHS amended 45 CFR 95.611(b)(2)(iii) to establish a $500,000 threshold for prior HHS approval of acquisition solicitation documents and contracts for ADP equipment or services for which States would seek enhanced federal matching funds (75 FR 66331). In the same rule, HHS also established at 45 CFR 95.611(b)(2)(iv) a $500,000 prior approval threshold for contract amendments for which States would seek enhanced Federal match (75 FR 66324). In the final rule titled ''Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems (90/10)'' (80 FR 75817, 75836 through 75837, December 4, 2015), 45 CFR 95.611(a)(2) was amended to establish a $500,000 threshold for prior approval of acquisitions related to ADP equipment and services matched at the enhanced rate for MMIS authorized under 42 CFR part 433, subpart C. There was previously no threshold dollar amount for prior approvals related to such acquisitions in 45 CFR 95.611(a)(2).

We are now proposing to amend 42 CFR 495.324(b)(2) and 495.324(b)(3) to align with current prior approval policy for MMIS and ADP systems at 45 CFR 95.611(a)(2)(ii), and (b)(2)(iii) and (iv), and to minimize burden on States. Specifically, we are proposing that the prior approval dollar threshold in § 495.324(b)(3) would be increased to $500,000, and that a prior approval threshold of $500,000 would be added to § 495.324(b)(2). We also are proposing minor amendments to the language of 495.324(b)(2) and (3) to better align it with the language of 45 CFR 95.611(b)(2)(iii) and (iv). In addition, in light of these proposed changes, we are proposing a conforming amendment to amend the threshold in § 495.324(d) for prior approval of justifications for sole source acquisitions to be the same $500,000 threshold. That threshold is currently aligned with the $100,000 threshold in current § 495.324(b)(3). We believe that amending § 495.324(d) to preserve alignment with § 495.324(b)(3) would reduce burden on States and maintain the consistency of our prior approval requirements. This proposal would not affect the other requirements that States must comply with when making acquisitions in support of the Medicaid Promoting Interoperability Program under the Federal provisions contained in 42 CFR part 495, subpart D, and specifically 42 CFR 495.348, regardless of conditions for prior approval.

We believe that this proposal would reduce burden on States by raising the prior approval thresholds and generally aligning them with the thresholds for prior approval of MMIS and ADP acquisitions costs. We are inviting public comments on this proposal.

b. Funding Availability to States To Conclude the Medicaid Promoting Interoperability Program

Under section 1903(a)(3)(F) and (t) of the Act, State Medicaid programs may receive FFP in expenditures for incentive payments to certain Medicaid providers to adopt, implement, upgrade, and meaningfully use CEHRT. In addition, FFP is available to States for reasonable administrative expenses related to administration of those incentive payments as long as the State meets certain conditions. Specifically, section 1903(a)(3)(F)(i) of the Act establishes 100 percent FFP to States for incentive payments to eligible Medicaid providers (described in section 1903(t)(1) and (2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT. Section 1903(a)(3)(F)(ii) of the Act establishes 90 percent FFP to States for administrative expenses related to administration of the incentive payments.

In § 495.320 and § 495.322, we provide the general rule that States may receive: (1) 100 Percent FFP in State expenditures for EHR incentive payments; and (2) 90 percent FFP in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers. Section 495.316 establishes State monitoring and reporting requirements regarding activities required to receive an incentive payment. Subject to § 495.332, the State is responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to receive an incentive payment for each payment year, as described in § 495.314.

To date, we have not established a date beyond which 90 percent FFP is no longer available to States for their expenditures related to administering the Medicaid Promoting Interoperability Program. In the Stage 1 final rule (75 FR 44319), we established that, in accordance with sections 1903(t)(4)(A)(iii) and (5)(D) of the Act, in no case may any Medicaid EP or eligible hospital receive an incentive payment after 2021 (42 CFR 495.310(a)(2)(v) and 495.310(f)).

Because December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability incentive payments to Medicaid EPs and eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year), we believe it is reasonable for States to conclude most administrative activities related to the Medicaid Promoting Interoperability Program, including submitting final required reports to CMS, by September 30, 2022. Therefore, we are proposing to amend § 495.322 to provide that the 90 percent FFP for Medicaid Promoting Interoperability Program administration would no longer be available for most State expenditures incurred after September 30, 2022.

We are proposing a later sunset date for the availability of 90 percent enhanced match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. We acknowledge that States have a responsibility to conduct audits of the payments made to Medicaid providers participating in the Medicaid Promoting Interoperability Program, in accordance with § 495.368, in order to combat fraud and abuse, and that States also must provide a process for EHR incentive payment appeals in accordance with § 495.370. We expect that these activities will require administration for some time after, but at most a year, beyond September 30, 2022. Because provider incentive payments could be disbursed up until December 31, 2021, we anticipate that States would need additional time to review provider risk factors, select samples, and conduct audits. Once post-payment audits are completed, States would also need time to work with any providers who choose to appeal their audit findings. Collectively, the post-payment audit process and/or appeals process could take several months, and in some cases might take more than one year. Therefore, we are proposing that the 90 percent FFP would continue to be available for State administrative expenditures related to Medicaid Promoting Interoperability Program audit and appeals activities until September 30, 2023. States would not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023.

States should be aware that under this proposal, they would need to incur the expenditures for which they would claim the 90 percent FFP for Medicaid Promoting Interoperability Program administrative activities no later than the sunset dates of September 30, 2022 or September 30, 2023, as applicable. This means that for States to claim the 90 percent FFP for goods and services related to Medicaid Promoting Interoperability Program administrative activities, States would have to ensure that the goods and services are provided no later than close of business September 30, 2022 or close of business September 30, 2023, as applicable. Thus, for example, if an amount that is related to administration of a Medicaid Promoting Interoperability Program audit or appeal has been obligated by September 30, 2023, but the good or service has not yet been furnished by that date, then the expenditure could not be claimed at the enhanced 90 percent FFP.

We are inviting public comments on this proposal, especially on whether the timelines proposed provide States with a reasonable amount of time to wind down their Medicaid Promoting Interoperability Program.

IX. Proposed Revisions of the Supporting Documentation Required for Submission of an Acceptable Medicare Cost Report

A. Background

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. In general, providers submit this information through annual cost reports [384] that cover a 12-month period of time. Under the regulations at 42 CFR 413.20(b) and 413.24(f), providers are required to submit cost reports annually, with the reporting period based on the provider's accounting year. For cost years beginning on or after October 1, 1989, section 1886(f)(1) of the Act and § 413.24(f)(4) of the regulations require hospitals to submit cost reports in a standardized electronic format, and the same requirement was later imposed for other types of providers.

All providers participating in the Medicare program are required under § 413.20(a) to maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Moreover, providers

[384] There are currently nine Medicare cost reports: The Hospital and Health Care Complex Cost Report, Form CMS–2552, OMB No. 0938–0050; the Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report, Form CMS–2540, OMB No. 0938–0463; the Home Health Agency Cost Report, Form CMS–1728, OMB No. 0938–0022; the Outpatient Rehabilitation Provider Cost Report, Form CMS–2088, OMB No. 0938–0037; the Independent Rural Health Clinic and Freestanding Federally Qualified Health Center Cost Report (prior to October 1, 2014), Form CMS–222, OMB No. 0938–0107; the Federally Qualified Health Center Cost Report (beginning on or after October 1, 2014), Form CMS–224, OMB No. 0938–1298; the Organ Procurement Organizations and Histocompatibility Laboratory, Form CMS–216, OMB No. 0938–0102; the Independent Renal Dialysis Facility Cost Report, Form CMS–265, OMB No. 0938–0236; and the Hospice Cost and Data Report, Form CMS–1984, OMB No. 0938–0758.

must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the hospital and related fields. Upon receipt of a provider's cost report, the Medicare Administrative Contractor (herein referred to as ''contractor'') reviews the cost report to determine its acceptability in accordance with § 413.24(f)(5). Each cost report submission by a provider to its contractor, including an amended cost report, is considered to be a separate cost report submission under § 413.24(f)(5). Each cost report submission requires the supporting documentation specified in § 413.24(f)(5)(i). A cost report submitted without the required supporting documentation is rejected under § 413.24(f)(5)(i). Under § 413.24(f)(5)(iii), when the cost report is rejected, it is deemed an unacceptable submission and treated as if it had never been filed.

Several provisions in the regulations requiring supporting documentation for the Medicare cost report to be acceptable need to be updated to reflect current practices, to improve the accuracy of these reports, and to facilitate more efficient contractor review of cost reports. The regulations at § 413.24(f)(5)(i) provides that a provider's cost report is rejected if the provider does not complete and submit the Provider Cost Reimbursement Questionnaire (a questionnaire independent of the cost report, OMB No. 0938–0301, also known as Form CMS–339). The Form CMS–339 requires the provider to submit supporting documents, as applicable, for items such as Medicare bad debt, approved educational activities, and cost allocation from a home office or chain organization.

Beginning in 2011, as cost report forms were updated for various provider types, the Form CMS–339 was incorporated as a worksheet in the Medicare cost report (the worksheet title and placement within the cost report vary by provider type), and is no longer submitted as a separate supporting document. The Form CMS–339 has been incorporated into all Medicare cost reports except for the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS–216. In section IX.B. of the preamble of this proposed rule, we are proposing to incorporate the Form CMS–339 into the OPO and Histocompatibility cost report, Form CMS–216.

The cost report worksheet that incorporated the Form CMS–339 continues to require the provider to submit supporting documents for Medicare bad debt, approved educational activities, and certain cost allocation information from a home office or chain organization, as applicable. However, our regulations at § 413.24(f)(5)(i) do not reflect that the Provider Cost Reimbursement Questionnaire, Form CMS–339, has been incorporated into the Medicare cost report as a worksheet because the regulations require the Form CMS–339 to be submitted as a supporting document to the cost report.

Section 413.24(f)(5)(i) also provides that a cost report is rejected for a teaching hospital if a copy of the Intern and Resident Information System (IRIS) diskette is not included as supporting documentation. However, diskettes are no longer used by providers to furnish this data to contractors.

Section 413.20 of the regulations requires providers to maintain sufficient financial records and statistical data for the proper determination of costs payable under the program as well as an adequate ongoing system for furnishing records needed to provide accurate cost data and other information capable of verification by qualified auditors. In accordance with § 413.20(d), the provider must furnish such information to the contractor as may be necessary to assure proper payment. Information from the provider relating to Medicaid days used in the calculation of DSH payments, charity care charges, uninsured discounts, and home office cost allocations are necessary to assure proper payment. While our regulations require that these supporting documents be maintained by the provider and furnished to the contractor to assure proper payment, § 413.24(f)(5) does not require submission of supporting documentation for Medicaid days used in the calculation of DSH payments, charity care charges, uninsured discounts, or home office cost allocations reported on a provider's cost report for the provider to have an acceptable cost report submission. These supporting documents are often subsequently requested by the contractor, and must be submitted by the provider in order to assure proper payment, which can delay payments and prolong audits.

Our specific proposals for revising our regulations are discussed below.

B. Proposed Revisions to Regulations

1. Provider Cost Reimbursement Questionnaire

Section 413.24(f)(5)(i) of the regulations provides that a provider's Medicare cost report is rejected for lack of supporting documentation if it does not include the Provider Cost Reimbursement Questionnaire (also known as Form CMS–339). As discussed in section IX.A. of the preamble of this proposed rule, beginning in 2011, as cost report forms were updated, the Provider Cost Reimbursement Questionnaire, Form CMS–339, was incorporated into all Medicare cost reports as a worksheet, except the OPO and Histocompatibility Laboratory cost report, Form CMS–216. In this proposed rule, we are proposing to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339, into the OPO and Histocompatibility Laboratory cost report, Form CMS–216. The incorporation of the Form CMS–339 into the Form CMS–216 will complete our incorporation of the Form CMS–339 into all Medicare cost reports.

In addition, in this proposed rule, we are proposing to revise § 413.24(f)(5)(i) by removing the reference to the Provider Cost Reimbursement Questionnaire so that § 413.24(f)(5)(i) no longer states that a cost report will be rejected for lack of supporting documentation if it does not include a Provider Cost Reimbursement Questionnaire (Form CMS–339). Furthermore, we are proposing to add language to the first sentence of § 413.24(f)(5)(i) to clarify that a provider must submit all necessary supporting documents for its cost report. We believe this proposal is consistent with the recordkeeping requirements in §§ 413.20 and 413.24.

2. Intern and Resident Information System (IRIS) Data

Section 413.24(f)(5)(i) also provides that a Medicare cost report for a teaching hospital is rejected for lack of supporting documentation if the cost report does not include a copy of the Intern and Resident Information System (IRIS) diskette.

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272, establishes a methodology for determining payments to hospitals for the GME programs (which is currently implemented in the regulations at 42 CFR 413.75 through 413.83). To account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals, section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the IME adjustment under the IPPS for hospitals that have residents in an approved GME program. The regulation regarding the calculation of this additional payment is located at 42 CFR 412.105. (We refer

readers to section IV.E. of the preamble of this proposed rule for additional background on direct GME and IME payments.)

In accordance with § 413.78(b) for direct GME and § 412.105(f)(1)(iii)(A) for IME, no individual may be counted as more than one full-time equivalent (FTE). A hospital cannot claim the time spent by residents training at another hospital; if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as a partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

In 1990, we established the IRIS, under the authority of sections 1886(d)(5)(B) and 1886(h) of the Act, in order to facilitate proper counting of FTE residents by hospitals that rotate their FTE residents from one hospital or nonprovider setting to another. Teaching hospitals use the IRIS to collect and report information on residents training in approved residency programs. Section 413.24(f)(5)(i) requires teaching hospitals to submit the IRIS data along with their Medicare cost reports in order to have an acceptable cost report submission. The IRIS can be downloaded from CMS' website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IRIS/index.html?redirect=/iris*. We are currently in the process of producing a new Extensible Markup Language (XML)-based IRIS file format that captures FTE resident count data consistent with the manner in which FTEs are reported on the Medicare cost report.

After receiving the IRIS data along with each teaching hospital's cost report, the contractors upload the data to a national database housed at CMS, which can be used to identify ''duplicates,'' that is, FTE residents being claimed by more than one hospital for the same rotation. Identifying duplicates allows the contractors to approach the hospitals that simultaneously claimed the same FTE, and correct the duplicate reporting on the respective hospitals' cost reports for direct GME and IME payment purposes.

Historically, we would collect the IRIS data from hospitals on a diskette, as referenced in § 413.24(f)(5)(i). Because diskettes are no longer used by providers to furnish these data to contractors, in this proposed rule, we are proposing to remove the reference in the regulations to a diskette and instead reference ''Intern and Resident Information System data.'' Specifically, we are proposing to amend § 413.24(f)(5)(i) by adding a new paragraph (A) to include this proposed revised language.

In addition, to enhance the contractors' ability to review duplicates and to ensure residents are not being double-counted, we believe it is necessary and appropriate to require that the total unweighted and weighted FTE counts on the IRIS for direct GME and IME respectively, for all applicable allopathic, osteopathic, dental, and podiatric residents that a hospital may train, must equal the same total unweighted and weighted FTE counts for direct GME and IME reported on Worksheet E–4 and Worksheet E, Part A. The need to verify and maintain the integrity of the IRIS data has been the subject of reviews by the Office of the Inspector General (OIG) over the years. An August 2014 OIG report cited the need for CMS to develop procedures to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–13–01014, August 2014). More recently, a July 2017 OIG report recommended that procedures be developed to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–15–01027, July 2017).

Therefore, effective for cost reports filed on or after October 1, 2018, we are proposing to add the requirement that IRIS data contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME and IME FTE residents reported in the cost report. Specifically, we are proposing to specify in a new paragraph (A) of § 413.24(f)(5)(i) that, effective for cost reports filed on or after October 1, 2018, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

3. Medicare Bad Debt Reimbursement

Under section 1861(v)(1) of the Act and the regulations at § 413.89, Medicare may reimburse a portion of the uncollectible deductible and coinsurance amounts to those entities eligible to receive reimbursement for Medicare bad debt. The Medicare Provider Reimbursement Manual (PRM–1, CMS Pub. 15–1), Chapter 3, provides guidance to providers that claim Medicare bad debt reimbursement.

Section 413.24(f)(5)(i) provides that an acceptable cost report submission requires the provider to submit a Provider Cost Reimbursement Questionnaire, Form CMS–339. The Form CMS–339, which has been incorporated into all Medicare cost reports (except the OPO and Histocompatibility Laboratory cost report, Form CMS–216, which we are now proposing to incorporate into the cost report, as discussed in section IX.B.1. of the preamble of this proposed rule), requires the provider to submit supporting documentation with the cost report to substantiate its claims for Medicare bad debt reimbursement. For example, the hospital cost report, which incorporated the Form CMS–339, instructs hospitals to submit a ''completed Exhibit 2 or internal schedules duplicating the documentation requested on Exhibit 2 to support the bad debts claimed'' (Section 4004.2 of CMS Pub. 15–2). This ''completed Exhibit 2 or internal schedules duplicating the documentation requested on Exhibit 2 to support the bad debts claimed'' is also known as the Medicare bad debt listing and requires information such as the patient's name, dates of service, the beneficiary's Medicaid status, if applicable, the date that collection effort ceased, and the deductible and coinsurance amounts.

Because the Provider Cost Reimbursement Questionnaire is incorporated into the cost report as a worksheet, the bad debt listing continues to be required for an acceptable cost report under § 413.24(f)(5). In this proposed rule, we are proposing to require that the Medicare bad debt listing correspond to the bad debt amount claimed in the provider's cost report, in order for the provider to have an acceptable cost report submission under § 413.24(f)(5). This is also consistent with a provider's recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, and will facilitate the contractor's review and verification of the cost report. Specifically, we are proposing to amend § 413.24(f)(5)(i) by adding a new paragraph (B) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a cost report would be rejected for lack of supporting documentation if it does not include a detailed bad debt listing that

corresponds to the bad debt amounts claimed in the provider's cost report.

4. Disproportionate Share Hospital (DSH) Payment Adjustment

The DSH payment adjustment provision under section 1886(d)(5)(F) of the Act was enacted by section 9105 of COBRA and became effective for discharges occurring on or after May 1, 1986. Under section 1886(d)(5)(F) of the Act, the primary method by which a hospital qualifies for a Medicare DSH payment is based on the hospital's disproportionate patient percentage, which is determined using a statutory formula. This statutory formula incorporates the hospital's number of patient days for patients who are eligible for Medicaid, but were not entitled to benefits under Medicare Part A (''Medicaid eligible days''), which hospitals are required to submit on their cost reports.

Currently, in order for a DSH eligible hospital to have an acceptable cost report submission, there is no requirement for the hospital to also submit a listing of its Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report, as a supporting document. DSH eligible hospitals have always been required to collect and maintain this data for completion of the cost report, and to submit it when requested. However, we are proposing that in order to have an acceptable cost report submission, DSH eligible hospitals must submit this supporting data with their cost reports. To ensure accurate DSH payments, additional information regarding Medicaid eligible days is required in order to validate the number of Medicaid eligible days the hospital reports in its cost report. Currently, when this information regarding Medicaid eligible days is not submitted by the DSH eligible hospitals with the cost report, contractors must request it. An audit may reveal an overstatement of a hospital's Medicaid eligible days. However, an audit of these data may not take place for more than a year after the cost report has been submitted, and tentative program reimbursement payments are often issued to a provider upon the submission of the cost report. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is not additional burden.

Requiring a provider to submit, as a supporting document with its cost report, a listing of the provider's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the DSH eligible hospital's cost report would provide contractors with the DSH eligible hospital's source document listing the Medicaid eligible days claimed on its cost report and would be consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to substantiate its costs. A requirement to submit this supporting documentation also would facilitate the contractor's review and verification of the cost report without the need to request additional data from the provider. This proposal would not affect a hospital's ability to submit an amended cost report, within 12 months after the hospital's cost report is due, that reflects updated information on Medicaid eligible patient days after the hospital receives updated Medicaid eligibility information from the State (CY 2016 OPPS/ASC final rule with comment period (80 FR 70560)).

Therefore, in this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, in order for a hospital eligible for a Medicare DSH payment adjustment to have an acceptable cost report submission in accordance with § 413.24(f)(5), the provider must submit a detailed listing of its Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the provider's cost report, as a supporting document with the provider's cost report. In addition, we are proposing that if the provider submits an amended cost report that changes its Medicaid eligible days, an amended listing or an addendum to the original listing of the provider's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the provider's amended cost report would also need to be submitted as a supporting document with the amended cost report.

Consistent with this proposal, we are proposing to amend § 413.24(f)(5)(i) by adding a new paragraph (C) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a DSH payment adjustment, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. If the hospital submits an amended cost report that changes its Medicaid eligible days, an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report would be required.

5. Charity Care and Uninsured Discounts

Section 3133 of the Affordable Care Act amended the Medicare DSH payment adjustment provision at section 1886(d)(5)(F) of the Act, and established section 1886(r) of the Act which provides for an additional payment that reflects a hospital's uncompensated care (which includes charity care and discounts given to uninsured patients who qualify under the hospital's charity care policy or financial assistance policy). In accordance with the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38208), starting in FY 2018, Worksheet S–10 of the cost report is used as a data source for calculating uncompensated care payments.

Currently there is no requirement for a DSH eligible hospital to submit supporting documentation with its cost report, to substantiate its charity care or discounts given to uninsured patients who qualify under the hospital's charity care policy or financial assistance policy, in order for its cost report submission to be acceptable in accordance with § 413.24(f)(5). Uncompensated care data reported on a hospital's cost report did not have an impact on the determination of uncompensated care payments before FY 2018 when the agency first began using Worksheet S–10 data to calculate uncompensated care payments. However, because the Worksheet S–10 data are now utilized to make uncompensated care payments to DSH-eligible hospitals, documentation to substantiate charity care or discounts given to uninsured patients who qualify under the hospital's charity care or financial assistance policy is needed to complete the cost report and to ensure there is no duplication when hospitals report Medicare bad debt, charity care, and uninsured discounts. All hospitals, including DSH eligible hospitals, have always been required to collect and maintain this data for completion of the cost report, and submit it when requested. However, we are now proposing that in order to have an acceptable cost report submission, DSH eligible hospitals must submit this supporting data with their cost reports. To ensure accurate uncompensated care payments, additional supporting information regarding charity care and uninsured discounts is required in order to validate the amounts reported in the cost report. Currently, when the documentation to support the charity care charges and uninsured discounts is not submitted by DSH eligible hospitals with the cost report, contractors must

request it. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is no additional burden.

We believe that requiring a DSH eligible hospital to submit, with its cost report, a detailed listing of its charity care and uninsured discounts that corresponds to the amount claimed in the hospital's cost report would be consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to substantiate its costs. This supporting documentation also would facilitate the contractor's review and verification of the cost report without the need to request additional data from the provider.

Therefore, in this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, in order for hospitals reporting charity care and/or uninsured discounts to have an acceptable cost report submission under § 413.24(f)(5), the provider must submit a detailed listing of charity care and/or uninsured discounts that contains information such as the patient name, dates of service, insurer (if applicable), and the amount of charity care and/or uninsured discount given that corresponds to the amount claimed in the hospital's cost report as a supporting document with the hospital's cost report.

Consistent with this proposal, we are proposing to amend § 413.24(f)(5)(i) by adding a new paragraph (D) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for hospitals reporting charity care and/or uninsured discounts, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the provider's cost report.

6. Home Office Allocations

A chain organization consists of a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization (Provider Reimbursement Manual 1 (PRM–1), CMS Pub. 15–1, Chapter 21, Section 2150). Chain organizations include, but are not limited to, chains operated by proprietary organizations and chains operated by various religious, charitable, and governmental organizations. A chain organization may also include business organizations which are engaged in other activities not directly related to health care.

When a provider claims costs on its cost report that are allocated from a home office (also known as a chain home office or chain organization), the Home Office Cost Statement constitutes the documentary support required of the provider to be reimbursed for home office costs in the provider's cost report as set forth in Section 2153, Chapter 21, of the PRM–1. Section 2153 states that each contractor servicing a provider in a chain must be furnished with a detailed Home Office Cost Statement as a basis for reimbursing the provider for cost allocations from a home office or chain organization. However, many cost reports that have home office costs allocated to them are submitted without a Home Office Cost Statement as a supporting document. In addition, there are home offices or chain organizations that are not completing a Home Office Cost Statement to support the costs they are allocating to the provider cost reports. Lack of this documentation should result in a disallowance of costs. It is our understanding that some providers paid under a PPS mistakenly believe that a Home Office Cost Statement is no longer required. However, the home office costs reported in the provider's cost report may have an impact on future ratesetting and payment refinement activities. We believe that requiring a home office or chain organization to complete a Home Office Cost Statement and a provider to submit, with its cost report, a copy of the Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report, is consistent with Section 2153 of the PRM–1 and would be consistent with a provider's recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require a provider to substantiate its costs.

Therefore, in this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, in order for a provider claiming costs on its cost report that are allocated from a home office or chain organization to have an acceptable cost report submission under § 413.24(f)(5), a Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report must be submitted as a supporting document with the provider's cost report. This proposal would facilitate the contractor's review and verification of the cost report without needing to request additional data from the provider. With our proposal, we anticipate more providers will submit the Home Office Cost Statement to support the amounts reported in their cost reports, in order to have an acceptable cost report submission. Because the existing burden estimate for a provider's cost report already reflects the requirement that providers collect, maintain, and submit this data, there is no additional burden.

Consistent with this proposal, we are proposing to amend § 413.24(f)(5)(i) by adding a new paragraph (E) to specify that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization, a cost report will be rejected for lack of supporting documentation if it does not include a Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report.

We are seeking public comment on all of our proposals.

X. Requirements for Hospitals To Make Public a List of Their Standard Charges via the Internet

In the FY 2015 IPPS/LTCH proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively), we discussed the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. We noted that section 2718(e) of the Public Health Service Act, which was enacted as part of the Affordable Care Act, requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act. We reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry.

We encouraged hospitals to undertake efforts to engage in consumer friendly communication of their charges to help patients understand what their potential

financial liability might be for services they obtain at the hospital, and to enable patients to compare charges for similar services across hospitals. We also stated that we expect that hospitals will update the information at least annually, or more often as appropriate, to reflect current charges. We further noted that we are confident that hospital compliance with this statutory transparency requirement will greatly improve the public accessibility of charge information. Finally, we stated that we would continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals, and patients being surprised by facility fees and physician fees for emergency room visits. We also are concerned that chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under section 2718(e) of the Public Health Service Act.

As one step to further improve the public accessibility of charge information, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate. This could be in the form of the chargemaster itself or another form of the hospital's choice, as long as the information is in machine readable format.

We also are considering other potential actions that would be appropriate, either under the authority of section 2718(e) of the Public Health Service Act or under other authority, to further our objective of having hospitals undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain at the hospital, and to enable patients to compare charges for similar services across hospitals. Therefore, we are seeking public comment on the following:

- Should ''standard charges'' be defined to mean: average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together (such as for an MS–DRG), as determined by the hospital based on its billing patterns; or the average discount off the chargemaster amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should ''standard charges'' be defined and reported for both some measure of the average contracted rate and the chargemaster? Or is the best measure of a hospital's standard charges its chargemaster?
- What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?
- Should health care providers be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? What can be done to better inform patients of these obligations? Should health care providers play any role in helping to inform patients of what their out-of-pocket obligations will be?
- Should we require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers? What corresponding regulatory changes would be necessary?

CMS is considering making information regarding noncompliance with section 2718(e) of the Public Health Service Act public and intends to consider this as well as additional enforcement mechanisms in future rulemaking. Therefore, we are seeking comment on the following:

- What is the most appropriate mechanism for CMS to enforce price transparency requirements? Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere? How should CMS assess hospital compliance? Should CMS publicize complaints regarding access to price information or review hospital compliance and post results? What is the most effective way for CMS to publicize information regarding hospitals that fail to comply? Should CMS impose civil money penalties on hospitals that fail to make standard charges publically available as required by section 2718(e) of the Public Health Service Act? Should CMS use a framework similar to the Federal civil penalties under 45 CFR 158.601, *et seq.* that apply to issuers that fail to report information and pay rebates related to medical loss ratios, as required by sections 2718(a) and (b) of the Public Health Service Act, or would a different framework be more appropriate?

In addition, we are seeking public comment on improving our understanding of out-of-pocket costs for patients with Medigap coverage, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do providers face in providing information about out-of-pocket costs to patients with Medigap? What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care? What State-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

We also note that, in the interest of public accessibility, we continue to post charge data for services furnished to Medicare beneficiaries covered under Medicare fee-for-service by diagnosis-related group for each IPPS hospital on our website. These charge data are based on the MEDPAR short-stay inpatient data and augmented with the provider-of-service data and hospital referral regions data to include provider characteristics and hospital referral region. For each hospital-DRG record, the charge data include total discharges for Medicare beneficiaries, average covered charges, average total payments, and average Medicare payments. Data are currently available for FYs 2011 through 2015 for the more than 3,000 IPPS hospitals within the 50 United States and District of Columbia. These data are available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient.html*.

XI. Proposed Revisions Regarding Physician Certification and Recertification of Claims

Our Medicare regulations at 42 CFR 424.11, which implement sections 1814(a)(2) and 1835(a)(2) of the Act, specify the requirements for physician statements that certify and periodically recertify as to the medical necessity of certain types of covered services provided to Medicare beneficiaries. The regulation provision under § 424.11(c) specifies that when supporting information for the required physician statement is available elsewhere in the records (for example, in the physician's progress notes), the information need not be repeated in the statement itself. The last sentence of § 424.11(c) further provides that it will suffice for the statement to indicate where the information is to be found.

As part of our ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers—and thereby free up resources that could be used to improve or enhance patient care—we have been made aware that the provisions of § 424.11(c) which state that it will suffice for the statement to indicate where the information is to be found may be resulting in unnecessary denials of Medicare claims. As currently worded, this last sentence of § 424.11(c) can result in a claim being denied merely because the physician statement technically fails to identify a specific location in the file for the supporting information, even when that information nevertheless may be readily apparent to the reviewer. We believe that continuing to require the location to be specified in this situation is unnecessary. Certifications and recertifications continue to be based on the criteria for the service being certified, and the medical record must contain adequate documentation of the relevant criteria for which the physician is providing certification or recertification, even if the precise location of the information within the medical record is not included. Moreover, the need for the precise location is becoming increasingly obsolete with the growing utilization of electronic health records (EHRs)—which, by their nature, are readily searchable. Accordingly, in this proposed rule, we are proposing to delete the last sentence of § 424.11(c). In addition, we are proposing to relocate the second sentence of § 424.11(c) (indicating that supporting information contained elsewhere in the provider's records need not be repeated in the certification or recertification statement itself) to the end of the immediately preceding paragraph (b), which describes similar kinds of flexibility that are currently afforded in terms of completing the required statement.

We are inviting public comments on our proposals.

XII. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.[385] While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC ''. . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,[386] which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.

[385] These statistics can be accessed at: *https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.*

[386] The draft version of the trusted Exchange Framework may be accessed at: *https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

• Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.

• Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.

• The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the IMPACT Act and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), inpatient rehabilitation hospitals (IRFs), inpatient psychiatric hospitals (IPFs), children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

• Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;

• Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and

• Hospitals, CAHs and HHAs, would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448), on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs must meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

We also published a final rule (81 FR 68688), on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs, where we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, a LTC hospital, a psychiatric facility, another LTC facility, a hospice, a health agency, or another community-based provider or practitioner. We specified that necessary information must include the following:

• Contact information of the practitioner responsible for the care of the resident;

• Resident representative information including contact information;

• Advance directive information;

• Special instructions or precautions for ongoing care;

• The resident's comprehensive care plan goals; and

• All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following

questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data was really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based API that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise and organized responses, including any relevant data and specific examples. However, respondents are not required to address every issue or respond to every question discussed in this Request for Information to have their responses considered. In accordance with the implementing regulations of the Paperwork Reduction Act at 5 CFR 1320.3(h)(4), all responses will be considered, provided they contain information CMS can use to identify and contact the commenter, if needed.

This Request for Information is issued solely for information and planning

purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party's expense.

We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2019 IPPS/LTCH PPS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential.

This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the public comments received, or a summary of those public comments.

XIII. 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 2018 ''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 2019 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*.

XIV. 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 2015 Medicare cost reports used to create the proposed FY 2019 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.

Processing year	Wage data year	PPS fiscal year
2018	2015	2019
2017	2014	2018
2016	2013	2017
2015	2012	2016
2014	2011	2015
2013	2010	2014
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2007 through FY 2019 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/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2019 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-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2019 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 2019 IPPS Update.

5. FY 2019 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and 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/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2019 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 as published in each year's update of the Medicare hospital inpatient prospective payment system. 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.*

Periods Available: FY 1985 through FY 2019.

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.*

Periods Available: FY 2005 through FY 2019 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.*

Periods Available: FY 1994 through FY 2019 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.*

Periods Available: FY 2005 through FY 2019 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/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2019 IPPS Update.

13. Hospital Readmissions Reduction Program Supplemental File

This file contains information on the calculation of the Hospital Readmissions Reduction Program (HRRP) payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction (AMI), pneumonia (PN) and heart failure (HF), coronary obstruction pulmonary disease (COPD), total hip arthroplasty (THA)/total knee arthroplasty (TKA), and coronary artery bypass grafting (CABG) and the proxy readmissions payment adjustment for each provider included in the program. In addition, the file contains information on the number of cases for each of the applicable conditions excluded in the calculation of the readmission payment adjustment factors. It also contains MS–DRG relative weight information to estimate the payment adjustment factors. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2019 IPPS Update.

14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2019. 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/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2019 IPPS Update.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In 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 for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from close hospitals, addressed in section IV.L.2. of the preamble of this proposed rule, are not subject to the Paperwork Reduction Act, as stated in section 5506 of the Affordable Care Act.

3. 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 (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request currently approved under OMB control number 0938–1022. OMB has currently approved 3,637,282 hours of burden and approximately $133 million under OMB control number 0938–1022, accounting for information collection burden experienced by 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2020 payment determination.[387] We no longer use OMB control number 0938–0918. Below, we describe the burden changes with regards to collection of information under OMB control number 0938–1022 for IPPS hospitals due to the proposals in this proposed rule.

In section VIII.A. of the preamble of this proposed rule, we discuss the following proposals that we expect to affect our collection of information burden estimates: (1) eCQM reporting and submission requirements for the CY 2019 reporting period/FY 2021 payment determination; (2) removal of eight chart-abstracted measures beginning with the CY 2019 reporting period/FY 2021 payment determination; and (3) removal of one chart-abstracted measure beginning with the CY 2020 reporting period/FY 2022 payment determination. Details on these proposals, as well as the expected burden changes, are discussed below.

This proposed rule also includes proposals with respect to claims-based measures to: (1) Remove 17 claims-based measures beginning with the CY 2018 reporting period/FY 2020 payment determination; (2) remove two claims-based measures beginning with the CY 2019 reporting period/FY 2021 payment determination; (3) remove one claims-based measure beginning with CY 2020 reporting period/FY 2022 payment determination; (4) remove one claims-based measure beginning with the CY 2021 reporting period/FY 2023 payment determination; (5) remove two structural measures beginning with the CY 2018 reporting period/FY 2020 payment determination; and (6) remove seven eCQMs beginning with CY 2020 reporting period/FY 2022 payment determination. As discussed further below, we do not expect these proposals to affect our information collection burden estimates.

b. Information Collection Burden Estimate for the Proposed Removal of Chart-Abstracted Measures

(1) Information Collection Burden Estimate for the Proposed Removal of Eight Chart-Abstracted Measures Beginning With the CY 2019 Reporting Period/FY 2021 Payment Determination

In sections VIII.A.5.b(2)(b) and VIII.A.5.b.(8)(b) of the preamble of this proposed rule, we are proposing to remove eight chart-abstracted measures (five National Healthcare Safety Network (NHSN)) hospital-acquired infection (HAI) measures and three clinical process of care measures) beginning with the CY 2019 reporting period/FY 2021 payment determination:

- National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717);
- National Healthcare Safety Network Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138);
- National Healthcare Safety Network Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139);
- National Healthcare Safety Network Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716);
- American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure-Specific Surgical Site Infection (SSI) Outcome Measure (Colon and Abdominal Hysterectomy SSI) (NQF #0753);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) (NQF #0495);
- Influenza Immunization (IMM–2) (NQF #1659); and
- Incidence of Potentially Preventable Venous Thromboembolism (VTE–6).

Because the burden associated with submitting data for the NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) is captured under separate OMB control number 0920–0666, we do not provide an independent estimate of the information collection burden associated with these measures for the Hospital IQR Program. Because the NHSN HAI measures will be retained in the HAC Reduction Program, we do not anticipate a reduction in data collection and reporting burden associated with the CDC NHSN's OMB control number 0920–0666. We note, however, that we anticipate a reduction in burden associated with the Hospital IQR Program validation activities we conduct for these NHSN HAI measures, as discussed further below.

We anticipate a reduction in information collection burden for all IPPS hospitals of 741,074 hours, or 225 hours per hospital, as a result of our proposals to remove the ED–1 and IMM–2 chart-abstracted measures beginning with the CY 2019 reporting period/FY 2021 payment determination. This estimate was calculated by considering the previously approved information collection burden estimate for reporting the combined global population set (ED–1, ED–2, and IMM–2) of 1,599,074 hours, minus the estimated information collection reporting burden for only the ED–2

[387] The information collection burden associated with submitting data for the HCP and HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) via the CDC's NHSN system is captured under a separate OMB control number, 0920–0666. The information collection burden associated with submitting data for the HCAHPS Survey measure is captured under OMB control number 0938–0981.

measure [388] ([15 minutes per record × 260 records per hospital per quarter × 4 quarters]/60 minutes per hour × 3,300 IPPS hospital = 858,000 hours). Through these calculations (1,599,074 hours − 858,000 hours), we estimate a reduction of 741,074 hours, or 225 hours per hospital per year (741,074 hours/3,300 hospitals) across all IPPS hospitals for the CY 2019 reporting period/FY 2021 payment determination if our proposals to remove the ED–1 and IMM–2 measures from the Hospital IQR Program are finalized as proposed.

We also anticipate our proposal to remove the VTE–6 measure would result in an information collection burden reduction of 304,997 hours for all IPPS hospitals, or 92 hours per hospital, for the CY 2019 reporting period/FY 2021 payment determination. We have previously estimated a reporting burden of 92 hours (7 minutes per record × 198 records per hospital per quarter × 4 quarters/60 minutes) per hospital per year, or 304,997 hours (92 hours per hospital × 3,300 hospitals) across all hospitals associated with abstracting and reporting VTE–6. Therefore, we estimate an information collection burden decrease of 304,997 hours for the CY 2019 reporting period/FY 2021 payment determination if our proposal to remove this measure from the Hospital IQR Program is finalized as proposed.

In summary, if our proposals in section VIII.A.5.b.(8) of the preamble of this proposed rule to remove IMM–2, ED–1, and VTE–6 are finalized as proposed, we estimate an information collection burden reduction of 1,046,071 hours (−741,074 hours for ED–1 and IMM–2 removal + −304,997 hours for VTE–6 removal) and approximately $38.3 million (1,046,071 hours × $36.58 per hour [389]) across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the CY 2019 reporting period/FY 2021 payment determination.

(2) Information Collection Burden Estimate for the Proposed Removal of One Chart-Abstracted Measure Beginning With the CY 2020 Reporting Period/FY 2022 Payment Determination

In section VIII.A.5.b.(8)(b) of the preamble of this proposed rule, we are proposing to remove the ED–2 measure (NQF #0497) beginning with the CY 2020 reporting period/FY 2022 payment determination. We anticipate removing this chart-abstracted measure would reduce the reporting burden for all IPPS hospitals by a total of 858,000 hours, or 260 hours per hospital. As discussed above, we estimate reporting the ED–2 measure takes approximately 260 hours (15 minutes per record × 260 records per hospital per quarter × 4 quarters/60 minutes = 260 hours) per hospital per year, or 858,000 hours (260 hours × 3,300 hospitals) across all IPPS hospitals. We, therefore, estimate an 858,000 hour information collection burden decrease for the CY 2020 reporting period/FY 2022 payment determination as a result of our proposal to remove this measure from the Hospital IQR Program.

In summary, if our proposal in section VIII.A.5.b.(8)(b) of the preamble of this proposed rule to remove ED–2 is finalized as proposed, we estimate an information collection burden reduction of 858,000 hours and approximately $31.4 million (858,000 hours × $36.58 per hour [390]) across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination.

(3) Information Collection Impacts on Data Validation Resulting From Chart-Abstracted Measure Removal

While we are not proposing any changes to our validation requirements related to chart-abstracted measures, if our proposals in section VIII.A.5.b.(2)(b) and section VIII.A.5.b.(8) of the preamble of this proposed rule to remove five NHSN HAIs and four clinical process of care measures are finalized as proposed, we believe that hospitals would experience an overall reduction in information collection burden associated with chart-abstracted measure validation beginning with the FY 2022 payment determination.

As noted in the FY 2016 IPPS/LTCH IPPS final rule (80 FR 49762 and 49763), we reimburse hospitals directly for expenses associated with submission of charts for clinical process of care measure data validation (we reimburse hospitals at 12 cents per photocopied page; for hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we reimburse hospitals at a rate of 40 cents per disc); we do not believe any additional information collection burden is associated with submitting this information via Web portal or PDF (79 FR 50346). Therefore, because we directly reimburse, we do not anticipate any net change in burden associated with the cost of submission of validation charts as a result of our proposals to remove four clinical process of care measures. Hospitals would no longer be required to submit, or be reimbursed for submitting, these data to CMS.

Because we are proposing to remove all of the NHSN HAI measures from the Hospital IQR Program and because hospitals selected for validation currently are required to submit validation templates for the NHSN HAI measures, we anticipate a reduction in information collection burden under the Hospital IQR Program associated with the NHSN HAI data validation effort. We note that the burden associated with data collection for the NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) is accounted for under the CDC NHSN OMB control number 0920–0666. Because the NHSN HAI measures will be retained in the HAC Reduction Program, we do not anticipate a change in data collection and reporting burden associated with this OMB control number due to our proposals. The data validation activities, however, are conducted by CMS. Since the measures were adopted into the Hospital IQR Program, CMS has validated the data for purposes of the Program. Therefore, this burden has been captured under the Hospital IQR Program's OMB control number 0938–1022. We have previously estimated a reporting burden of 80 hours (1,200 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for chart-abstracted measure validation per year to submit the CLABSI and CAUTI templates, and 64 hours (960 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for chart-abstracted measure validation per year to submit the MRSA and CDI templates. We, therefore, estimate a total validation burden decrease of 43,200 hours ([−80 hours per hospital to submit CLABSI and CAUTI templates + −64 hours per hospital to submit MRSA and CDI templates] × 300 hospitals selected for validation) and approximately $1.6 million (43,200 hours × $36.58 per hour [391]) for the FY 2022 payment

[388] Estimated 15 minutes per case for reporting ED–2 measure based on average Clinical Data Abstraction Center abstraction times for 3Q 2016, 4Q 2016, and 1Q 2017 discharge data.

[389] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[390] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[391] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of

determination because of the removal of these measures from the Hospital IQR Program and the secondary effects on validation. We note that we are proposing that the HAC Reduction Program will begin validation of these NHSN HAI measures as discussed in section IV.J. of the preamble of this proposed rule.

c. Information Collection Burden Estimate for Proposed Removal of Two Structural Measures

In sections VIII.A.5.a. and b.(1) of the preamble of this proposed rule, we are proposing to remove two structural measures (Hospital Survey on Patient Safety Culture and Safe Surgery Checklist Use) beginning with the CY 2018 reporting period/FY 2020 payment determination. We anticipate removing these measures will result in a minimal information collection burden reduction for hospitals. Specifically, we do anticipate a very slight reduction in information collection burden associated with the proposed removal of the Safe Surgery Checklist measure because completion of this measure takes hospitals approximately two minutes each year (77 FR 53666). Similarly, we anticipate a very slight reduction in information collection burden associated with the proposed removal of the Patient Safety Checklist measure (80 FR 49762 through 49873). Consistent with previous years (80 FR 49762), we estimate a collection of information burden of 15 minutes per hospital to report all four previously finalized structural measures and to complete other forms (such as the Extraordinary Circumstances Extension/Exemption Request Form). Therefore, our information collection burden estimate of 15 minutes per hospital remains unchanged because we believe the reduction in information collection burden associated with removing these two structural measures is sufficiently minimal that it will not substantially impact this estimate, and we want to retain a conservative estimate of the information collection burden associated with the use of our forms.

d. Burden Estimate for Proposed Removal of Claims-Based Measures

In section VIII.A.5.b.(2)(a), (3), (4), (6), and (7) of the preamble of this proposed rule, we are proposing to remove the following 17 claims-based measures beginning with the CY 2018 reporting period/FY 2020 payment determination:

- Patient Safety and Adverse Events Composite Measure (PSI 90) (NQF #0531);
- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (READM–30–AMI);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (READM–30–COPD);
- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (READM–30–CABG);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Heart Failure Hospitalization (NQF #0330) (READM–30–HF);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization (NQF #0506) (READM–30–PN);
- 30-day Risk-Standardized Readmission Rate Following Stroke Hospitalization (READ–30–STK;
- Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1551) (READM–30–THA/TKA);
- Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older (NQF #0230) (MORT–30–AMI);
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229) (MORT–30–HF);
- Medicare Spending Per Beneficiary (MSPB)—Hospital (NQF #2158);
- Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment);
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment);
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment);
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment); and
- Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment).

In addition, we are proposing to remove two claims-based measures beginning with the CY 2019 reporting period/FY 2021 payment determination: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893); and (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (NQF #0468). We also are proposing to remove one claims-based measure, Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery measure (NQF #2558), beginning with the CY 2020 reporting period/FY 2022 payment determination, and one claims-based measure, Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty, beginning with the CY 2021 reporting period/FY 2023 payment determination.

Because these claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, we do not anticipate that removing these measures will affect information collection burden on hospitals. However, we refer readers to section VIII.A.5.b.(2)(a), (3), (4), (6) and (7) of the preamble of this proposed rule for a discussion of the reduction in costs associated with these measures unrelated to the information collection burden.

e. Information Collection Burden Estimate for Proposed Removal of eCQMs

In section VIII.A.5.b.(9) of the preamble of this proposed rule, we are proposing to remove the following seven eCQMs from the eCQM measure set beginning with the CY 2020 reporting period/FY 2022 payment determination:

- Primary PCI Received within 90 Minutes of Hospital Arrival (AMI–8a);
- Home Management and Plan of Care Document Given to Patient/Caregiver (CAC–3);
- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) (NQF #0495); [392]
- Hearing Screening Prior to Hospital Discharge (EHDI–1a) (NQF# 1354);
- Elective Delivery (PC–01) (NQF #0469);
- Stroke Education (STK–08); and
- Assessed for Rehabilitation (STK–10) (NQF #0441).

Because these eCQMs being proposed for removal were among a set of 15 eCQMs available for reporting, we believe that reducing the number of

$18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[392] Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1) is proposed for removal in both chart-abstracted and eCQM forms.

eCQMs from which hospitals choose would enable hospitals to focus on and maintain a smaller subset of measures (8 instead of 15), but this would not have an effect on the burden of submitting information to CMS. Hospitals will still be required to submit 4 eCQMs of their choice from the eCQM measure set. While the information collection burden would not change, we refer readers to section VIII.A.4.b. of the preamble of this proposed rule where we acknowledge that costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Program requirements.

f. Information Collection Burden Estimates for the Proposed Updates to the eCQM Reporting Requirements

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361), we finalized eCQM reporting requirements, such that hospitals submit one, self-selected calendar quarter of data for 4 eCQMs in the Hospital IQR Program measure set for the CY 2018 reporting period/FY 2020 payment determination. In section VIII.A.10.d.(2) of the preamble of this proposed rule, we are proposing to require that hospitals continue to submit one, self-selected calendar quarter of data for 4 eCQMs in the Hospital IQR Program measure set for the CY 2019 reporting period/FY 2021 payment determination. Therefore, we believe the burden estimate of 40 minutes per hospital per year (10 minutes per record × 4 eCQMs × 1 quarter) associated with eCQM reporting requirements finalized for the CY 2018 reporting period/FY 2020 payment determination will also apply to the CY 2019 reporting period/FY 2021 payment determination.

g. Information Collection Burden Estimate for the Proposed Modifications to EHR Certification Requirements

In section VIII.A.10.d.(3) of the preamble of this proposed rule, we are proposing to update the EHR certification requirements by requiring the use of EHR technology certified to the 2015 Edition beginning with the CY 2019 reporting period/FY 2021 payment determination, to align with the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and CAHs. We do not expect this proposal to affect our information collection burden estimates because this proposal does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, we refer readers to Appendix I.K. of the preamble of this proposed rule.

h. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate: (1) A total information collection burden reduction of 1,046,138 hours (−1,046,071 hours due to the proposed removal of ED–1, IMM–2, and VTE–6 measures for the CY 2019 reporting period/FY 2021 payment determination and −67 hours for no longer collecting data for the voluntary Hybrid HWR measure [393]) and a total cost reduction related to information collection of approximately $38.3 million (−1,046,138 hours × $36.58 per hour [394]) for the CY 2019 reporting period/FY 2021 payment determination; and (2) a total information collection burden reduction of 901,200 hours (−858,000 hours due to the proposed removal of ED–2—43,200 hours due to no longer needing to validate NHSN HAI measures under the Hospital IQR Program) and a total information collection cost reduction of approximately $33 million (−901,200 hours × $36.58 per hour [395]) for the CY 2020 reporting period/FY 2022 payment determination. These are the total information collection burden reduction estimates for which we are requesting OMB approval under OMB number 0938–1022.

HOSPITAL IQR PROGRAM CY 2019 REPORTING PERIOD/FY 2021 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control No. 0938–1022 for CY 2019 reporting period/FY 2021 payment Determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly proposed annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Reporting on Emergency department throughput (ED–1)/Immunizations (IMM–2)	13	4	3,300	260	225	858,000	1,599,074	−741,074
Venous thromboembolism (VTE)	7	4	3,300	198	92	0	304,997	−304,997
Voluntary HWR Reporting [396]	10	4	100	1	0.67	0	67	−67

Total Change in Information Collection Burden Hours: −1,046,138.
Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−1,046,138) = −$38,267,728.

[393] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid HWR measure for the CY 2018 reporting period/FY 2020 payment determination. We estimated that approximately 100 hospitals would voluntarily report data for this measure, resulting in a total burden of 67 hours across all hospitals for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for one year, voluntary collection of this data would no longer occur, beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years, resulting in a reduction in burden of 67 hours across all hospitals.

[394] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[395] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

HOSPITAL IQR PROGRAM CY 2020 REPORTING PERIOD/FY 2022 PAYMENT DETERMINATION INFORMATION COLLECTION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control No. 0938–1022 for CY 2020 reporting period/FY 2022 payment determination							
	Estimated time per record (minutes)	Number reporting quarters per year	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly proposed annual burden (hours) across IPPS hospitals	Previously finalized annual burden (hours) across IPPS hospitals	Net difference in annual burden hours
Reporting on Emergency department throughput (ED–2 only)	15	4	3,300	260	260	0	858,000	−858,000
HAI Validation Templates (CLABSI, CAUTI)	1,200	4	300	1	80	0	24,000	−24,000
HAI Validation Templates (MRSA, CDI)	960	4	300	1	64	0	19,200	−19,200
Total Change in Information Collection Burden Hours: −901,200								
Total Cost Estimate: Updated Hourly Wage ($36.58) × Change in Burden Hours (−901,200) = $32,965,896								

4. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

a. Background

As discussed in sections 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. Below we discuss only changes in burden that would result from the proposals in this proposed rule.

b. Proposed Revision of Time Estimate for Structural and Web-Based Tool Measures for the FY 2021 Program Year and Subsequent Years

In this proposed rule, we are proposing a revision to our burden calculation methodology. With all the parameters considered when PCHs submit data on PCHQR Program measures (training of appropriate staff members on National Healthcare Safety Network (NHSN) reporting and the CMS Web Measures Tool for the reporting of the clinical process/oncology care measures; the time required for collection and aggregation of data; and the time required for reporting of the data by the PCH's representative), we strive to achieve continuity in how we calculate and analyze burden data. In prior years, we have based our burden estimates on the notion that all 11 PCHs would report on all measures for all cases (78 FR 50958). These assumptions were made in order to be as comprehensive as possible given a lack of PCH-specific data available at the time. However, we believe it is more appropriate to use estimates developed using data available in other quality reporting programs wherever possible, because we believe these estimates will provide a more accurate estimate of burden associated with data collection and reporting. Our proposal to update the estimate the time required to collect and report data for structural measures and measures that use a web-based tool is discussed below.

We initially adopted five clinical process/cancer specific treatment measures that utilized a web-based tool for the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50844). In that rule, we did not specify burden estimates based on the measure type, but instead provided estimates ''for submitting all quality measure data'' (78 FR 50958). Since then, we have been able to better understand and differentiate the various levels of effort associated with data abstraction and submission for specific types of measures. Moreover, in understanding that certain measure types prove more burdensome than others (that is, chart-abstracted measures), we believe it is necessary to provide burden estimates that better reflect with the type of measure being discussed.

Using historical data from its validation contractor, the Hospital IQR Program has previously estimated that it takes 15 minutes per hospital to report on four structural measures (80 FR 49762). We believe this estimate is appropriate for the PCHQR Program because data submission for measures that utilize a web-based tool is similar to the data submission for a structural measure, in that both types of measures use the same reporting mechanism, the QualityNet Secure Portal. In addition, we wish to account for the time associated with data collection and aggregation for individual measures when considering burden, and believe 15 minutes per measure is an appropriately conservative estimate for the measures submitted via a web-based tool in the PCHQR Program. Therefore, we are proposing to apply this burden estimate to four measures that utilize a web-based tool: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389).

We are inviting public comment on our proposal to utilize a burden estimate of 15 minutes per measure, per PCH, with respect to the burden estimates we discuss below for the FY 2021 program year and subsequent years.

[396] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid HWR measure for the CY 2018 reporting period/FY 2020 payment determination. We estimated that approximately 100 hospitals would voluntarily report data for this measure, resulting in a total burden of 67 hours across all hospitals for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for one year, voluntary collection of this data would no longer occur beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years resulting in a reduction in burden of 67 hours across all hospitals.

c. Estimated Burden of PCHQR Program Proposals for the FY 2021 Program Year

In section VIII.B.3. of the preamble of this proposed rule, we are proposing to remove six measures beginning with the FY 2021 program year—four web-based, structural measures: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389), and two chart-abstracted, NHSN measures: (5) NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and (6) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139). In addition, in section VIII.B.4.b. of the preamble of this proposed rule, we are proposing to adopt one claims-based measure, 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188), beginning with the FY 2021 program year. If these proposals are finalized, the PCHQR Program measure set would consist of 13 measures for the FY 2021 program year.

We anticipate our proposal to remove four web-based, structural measures will reduce the burden associated with quality reporting on PCHs. If our proposal to apply the burden estimate of 15 minutes per measure to the four web-based, structural measures is finalized as proposed, we estimate a reduction of 1 hour (or 60 minutes) per PCH (15 minutes per measure × 4 measures = 60 minutes), and a total annual reduction of approximately 11 hours for all 11 PCHs (60 minutes × 11 PCHs/60 minutes per hour), due to the proposed removal of these four measures.

We anticipate that the proposed removal of the two NHSN measures: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and (2) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) will result in a burden decrease. Historically, we have accounted for the burden associated with collecting and reporting data for the Catheter-Associated Urinary Tract Infections (CAUTI) and Central Line-Associated Bloodstream Infection (CLABSI) National Healthcare Safety Network measures as though they were standalone chart-abstracted measures.[397] Specifically, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667), we originally estimated the burden for reporting three chart-abstracted cancer measures and two NHSN CDC measures (CLABSI and CAUTI) at approximately 6,293.5 hours annually for each PCH, or 69,228.5 burden hours annually for all 11 PCHs. Using this estimate, we estimated 1,259 burden hours per measure (6,294 hours/5 measures = 1,258.8 hours per measure). As such, if our proposal to remove the CAUTI and CLABSI measures is finalized as proposed, we estimate an annual burden reduction of 2,518 hours per PCH (1,259 hours × 2 measures = 2,518 hours) and an annual burden reduction of 27,698 hours across all eleven PCHs (2,518 hours per PCH × 11 PCHs = 27,698 hours).

We do not anticipate any increase in burden on PCHs related to our proposal to adopt the claims-based 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188) beginning with the FY 2021 program year. Because this measure is claims-based and therefore does not require facilities to submit any additional data, we do not believe there is any increase in burden associated with this proposal.

In summary, if our proposals to remove six measures and to modify our burden estimation methodology for measures that utilize a web-based submission tool are finalized as proposed, we estimate a total reduction of 27,709 hours of burden per year for all 11 PCHs (−27,698 hours for the removal of the CAUTI & CLABSI measures − 11 hours for the removal of the four web-based, structural measures = 27,709 total hours) beginning with the FY 2021 program year. Coupled with our estimated salary costs, we estimate that these proposed changes would result in a reduction in annual labor costs of $1,013,595 (27,709 hours × $36.58 hourly labor cost[398]) across the 11 PCHs beginning with the FY 2021 PCHQR Program. The burden associated with these reporting requirements is currently approved under OMB control number 0938–1175. The information collection will be revised and submitted to OMB.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.I. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to remove four claims-based measures effective with the effective date of the FY 2019 IPPS/LTCH PPS final rule. Because these claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, we do not anticipate removing these measures will increase or decrease the reporting burden on hospitals. However, we believe removal of these measures from the Hospital VBP Program will reduce other costs associated with the program, such as: (1) Costs for health care providers and clinicians to track the confidential feedback preview reports and publicly reported information on the measures in more than one program; (2) costs for CMS to analyze, and publicly report the measure data in multiple programs; and (3) confusion for beneficiaries to see public reporting on the same measures in different programs.

In addition, in this proposed rule, we are proposing to remove six chart-abstracted measures beginning with the FY 2021 program year. Because these chart-abstracted measures used data required for and collected under the Hospital IQR Program (OMB control number 0938–1022), there was no additional data collection burden associated these measures under the Hospital VBP Program. Therefore, we do not anticipate removing these measures will increase or decrease the reporting burden on hospitals. However, we believe removal of these measures from the Hospital VBP Program will reduce other costs associated with the program, such as: (1) Costs for health care providers and clinicians to track the confidential feedback preview reports and publicly reported information on the measures in more than one program; (2) costs for CMS to analyze, and publicly report the measures' data in multiple programs; and (3) confusion for beneficiaries to see public reporting on the same measures in different programs. We note that we are proposing to remove seven claims-based measures from the Hospital IQR

[397] We note that the Centers for Disease Control and Prevention (CDC), the owner of the NHSN system, maintains its own OMB control number, 0920–0666, that estimates the burden associated with reporting data for the measures retained in the PCHQR program, that utilize the NHSN system. We have not independently accounted for the burden associated with adopting subsequent measures utilizing the NHSN system (that is, Colon and Abdominal Hysterectomy SSI; CDI; MRSA Bacteremia; and Influenza Vaccination Coverage Among Healthcare Personnel (HCP) measures) because the burden associated with reporting these measures is captured under the aforementioned OMB control number.

[398] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38504 through 38505), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

Program, which have been finalized previously for, and will remain in, the Hospital VBP Program. However, we do not believe retaining these claims-based measures in the Hospital VBP Program will create any additional burden for hospitals because the measure data will continue to be collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes.

6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in section VIII.C.5. of the preamble of this proposed rule, we are proposing to remove two measures from the LTCH QRP beginning with the FY 2020 LTCH QRP and to remove one measure from the LTCH QRP beginning with the FY 2021 LTCH QRP.

In section VIII.C.5.a. and b. of the preamble of this proposed rule, we are proposing to remove two CDC NHSN measures: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure—beginning with the FY 2020 LTCH QRP. LTCHs would no longer be required to submit data on these measures beginning with October 1, 2018 admissions and discharges. As a result, the burden and cost specifically for LTCHs for complying with the requirements of the LTCH QRP would be reduced. While the overall burden estimates are accounted for under OMB control number (0920–0666), to specifically account for burden reductions, the CDC provided more detailed estimates for LTCH reporting on the data for the measures we are proposing to remove.

Based on estimates provided by the CDC, which is based on the frequency of actual reporting on such data, we estimate that the removal of the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) would result in a 3-hour (15 minutes per MRSA submission × 12 estimated submissions per LTCH per year) reduction in clinical staff time annually to report data, which equates to a decrease of 1,260 hours (3 hours burden per LTCH per year × 420 total LTCHs) in burden for all LTCHs. Given 10 minutes of registered nurse time at $69.40 per hour, and 5 minutes of medical records or health information technician time at $39.86 per hour, for the submission of MRSA data to the NHSN per LTCH per year, we estimate that the total cost of complying with the requirements of the LTCH QRP would be reduced by $178.66 per LTCH annually, or $75,037.20 for all LTCHs annually.

Applying the same approach on burden reduction estimations, we estimate that the removal of the National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure from the LTCH QRP would result in a 4.4 hour (22 minutes per VAE submission × 12 estimated submissions per LTCH per year) reduction in clinical staff time to report data, which equates to a decrease of 1,848 hours (4.4 hours burden per LTCH per year × 420 total LTCHs) in burden for all LTCHs. Given the registered nurse hourly rate of $69.40 per hour, and medical records or health information technician rate of $39.86 per hour for the submission of VAE data to the NHSN per LTCH per year, we estimate that the total cost of complying with the LTCH QRP would be reduced by $293.54 per LTCH annually, or $123,288.48 for all LTCHs annually.

In addition, in section VIII.C.5.c. of the preamble of this proposed rule, we are proposing to remove the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2021 LTCH QRP. LTCHs would no longer be required to submit data on this measure beginning with October 1, 2018 admissions and discharges. As a result, the estimated burden and cost for LTCHs for complying with requirements of the LTCH QRP would be reduced. Specifically, we believe that there would be a 1.8 minute reduction in clinical staff time to report data per patient stay. We estimate 136,476 discharges from 420 LTCHs annually. This equates to a decrease of 4,094 hours in burden for all LTCHs (0.03 hours per assessment × 136,476 discharges). Given 1.8 minutes of registered nurse time at $69.40 per hour completing an average of 325 sets of LTCH CARE Data Set assessments per LTCH per year, we estimate that the total cost would be reduced by $676.53 per LTCH annually, or $284,143.03 for all LTCHs annually. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1163.

Overall, the cost associated with the proposed changes to the LTCH QRP is estimated at a reduction of $1,148.73 per LTCH annually or $482,468.71 for all LTCHs.

7. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In section IV.J. 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 adopt any new measures into the HAC Reduction Program. However, the Hospital IQR Program is proposing to remove the claims-based Patient Safety and Adverse Events Composite (PSI 90) and five NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA, and SSI). These measures had been previously adopted for, and will remain in, the HAC Reduction Program.

We do not believe that retaining the claims-based PSI 90 measure in the HAC Reduction Program will create any additional burden for hospitals because it will continue to be 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, and therefore will not impact our burden estimates.

We anticipate the proposed discontinuation of the HAI measure validation process under the Hospital IQR Program will result in a net burden decrease to the Hospital IQR Program, but will result in an off-setting net burden increase to the HAC Reduction Program because hospitals selected for validation will continue to be required to submit validation templates for the HAI measures. Therefore, if our proposals in section VIII.A.5.b.(2)(b) of the preamble of this proposed rule to remove the HAI chart-abstracted measures from the Hospital IQR Program are adopted, data validation for the measures will transfer to the HAC Reduction Program, and this is will result in a net neutral transfer of 43,200 hours and approximately $1.6 million with no overall net increase in burden.

Under the Hospital IQR Program, we have previously estimated a reporting burden of 80 hours (1,200 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for validation per year to submit the CLABSI and CAUTI templates, and 64 hours (960 minutes per record × 1 record per hospital per quarter × 4 quarters/60 minutes) per hospital selected for validation per year to submit the MRSA and CDI templates.

We therefore estimate a total burden shift of 43,200 hours ([80 hours per hospital to submit CLABSI and CAUTI templates + 64 hours per hospital to submit MRSA and CDI templates] × 300 hospitals selected for validation) and approximately $1.6 million (43,200 hours × $36.58 per hour [399]) as a result of our proposals to discontinue HAI validation under the Hospital IQR Program and begin a validation process under the HAC Reduction Program.

8. ICRs Relating to the Hospital Readmissions Reduction Program

In section IV.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital Readmissions Reduction Program. In this proposed rule, we are not proposing to adopt any new measures into the Hospital Readmissions Reduction Program. However, we are proposing to remove six claims-based measures from the Hospital IQR Program, which have been finalized previously for, and will remain in, the Hospital Readmissions Reduction Program. We do not believe that these claims-based measures remaining in the Hospital Readmissions Reduction Program will create any additional burden for hospitals because they will continue to be collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes.

9. ICRs for the Promoting Interoperability Programs

a. Background and Proposed Update to Hourly Wage Rate

In section VIII.D. of the preamble of this proposed rule, we are proposing a new performance-based scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS for the Medicare Promoting Interoperability Program. We are also proposing: To change the EHR reporting period in CYs 2019 and 2020; to establish the CQM reporting period and criteria for CY 2019, proposing the removal of eight CQMs beginning in CY 2020; and to codify the policies for subsection (d) Puerto Rico hospitals to participate in the Medicare Promoting Interoperability Program for eligible hospitals, including policies previously implemented through program instruction. We are retaining the requirement for the 2015 Edition of CEHRT to be used beginning in CY 2019.

In prior rules (81 FR 57260), we have estimated that the electronic reporting of CQM data could be accomplished by staff with a mean hourly wage of $16.42 per hour.[400] Because this wage rate is based on Bureau of Labor Statistics (BLS) data dating to 2012, we are proposing to update the wage rate to the most recent data available from the BLS, which is the 2016 wage rate of $19.93.[401] We are calculating the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. This is an estimated adjustment, since both fringe benefits and overhead costs vary significantly from employer-to-employer and the methods of estimating such costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.44 × 2 = $39.86) to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs. We refer readers to the Hospital IQR Program discussion in section XIV.B.3. of the preamble of this proposed rule, above, for more information regarding the information collection burden related to reporting of CQMs.

b. Burden Estimates

In sections VIII.D.5. and 6. of the preamble of this proposed rule, we are proposing a new scoring methodology for eligible hospitals and CAHs that attest to CMS for the Promoting Interoperability Program, and the addition of two new opioid measures that would be optional in 2019. This scoring approach would require eligible hospitals and CAHs to report by attestation on only six measures. We consider this scoring methodology to be based more on performance and not solely on whether an eligible hospital or CAH meets the thresholds for measures. We estimate that the new scoring methodology would reduce the necessary response time by .25 hours. This is a reduction to the previous burden estimate provided in the 2015 EHR Incentive Programs final rule (80 FR 62928). We are updating the burden estimate to take into account the reduced burden associated with the proposed new requirements for eligible hospitals and CAHs for Stage 3 of meaningful use. We believe the burden would be different for eligible hospitals that attest to a State for purposes of receiving a Medicaid incentive payment because the existing Stage 3 requirements would continue to apply to them. We note that under section 101(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10), the Medicare EHR Incentive Program was sunset for EPs in 2018, and now many of these EPs are subject to the requirements of the Quality Payment Program (QPP). Currently the burden is estimated at $388,408,189 annually. We estimate the burden for all participants in the Medicare and Medicaid Promoting Interoperability Programs represents a total cost of $61,113,527.80, which is a reduction of $327,294,661 annually. We also note that the currently approved burden in hours are 4,230,155 and as a result of this proposal we believe it will be reduced to 623,562.19 hours. This burden reduction would occur as a result of the reduced numbers of EPs and the new scoring methodology for eligible hospitals and CAHs proposed in this proposed rule. The burden estimate includes subsection (d) Puerto Rico hospitals. Below is the burden table where we take into account these changes and the burden that would ensue as a result of the changes. Please note that the information collection request (OMB Control number 0938–1278) is being revised and will be submitted to OMB.

BURDEN AND COST ESTIMATES ASSOCIATED WITH INFORMATION COLLECTION

Reg section	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.24(d)—Objectives/Measures (Medicaid EPs)	80,000	80,000	7.43	594,400	100	$59,440,000

[399] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[400] Occupational Outlook Handbook. Available at: *http://www.bls.gov/oes/2012/may/oes292071.htm.*

[401] Occupational Outlook Handbook. Available at: *https://www.bls.gov/oes/current/oes292071.htm.*

BURDEN AND COST ESTIMATES ASSOCIATED WITH INFORMATION COLLECTION—Continued

Reg section	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total cost ($)
§ 495.24(d)—Objectives/Measures Medicaid (eligible hospitals/CAHs) ...	133	133	7.43	988.19	67.25	66,455.78
§ 495.24(e)—Objectives/Measures Medicare (eligible hospitals/CAHs) ..	3300	3300	7.18	23,694	67.25	1,593,421.50
§ 495.316—Quarterly Reporting (Medicaid)	56	224	20	4,480	3.047	13,650.56
Totals	83,489	83,489	.....	623,562.19	.....	$61,113,527.80

There are 3,300 eligible hospitals and CAHs that attest to CMS (Medicare-only and dual-eligible) under the Medicare Promoting Interoperability Program. Therefore, the total estimated annual cost burden for all eligible hospitals and CAHs in the Medicare Promoting Interoperability Program to attest to meaningful use would be $,1,593,421.5 (3,300 eligible hospitals and CAHs × 7 hours 18 minutes × $67.25).[402]

We are proposing that the new scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS would be optional for States to implement through changes to their State Medicaid HIT Plans approved by CMS for eligible hospitals participating in their Medicaid Promoting Interoperability Program. If States choose not to align, eligible hospitals in those States would continue to attest to the objectives and measures as currently specified under § 495.24(d). Extending this option to States would allow them flexibility to benefit from the improvements to meaningful use scoring outlined in this proposed rule, if they so choose. If States choose to take this option, we anticipate the same burden reduction for Medicaid eligible hospitals as discussed above, but a significant burden increase for States that would have to overhaul their systems to collect data. If States do not take the option, they would face no burden increase or decrease.

In section VIII.D.7. of the preamble of this proposed rule, we are proposing the EHR reporting periods in CYs 2019 and 2020 for new and returning participants attesting to CMS or their State Medicaid agency would be a minimum of any continuous 90-day period within each of the CYs 2019 and 2020. This would mean that EPs that attest to a State for the State's Medicaid Promoting Interoperability Program and eligible hospitals and CAHs attesting to CMS or the State's Medicaid Promoting Interoperability Program would attest to meaningful use of CEHRT for an EHR reporting period of a minimum of any continuous 90-day period from January 1, 2019 through December 31, 2019 and from January 1, 2020 through December 31, 2020, respectively. The applicable incentive payment year and payment adjustment years for the EHR reporting periods in 2019 and 2020, as well as the deadlines for attestation and other related program requirements, would remain the same as established in prior rulemaking. We are proposing corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4. We do not expect these proposals to affect our burden estimates because we have never required a different EHR reporting period.

In section VIII.D.9. of the preamble of this proposed rule we are proposing that the reporting period for Medicare and Medicaid eligible hospitals and CAHs that report CQMs electronically would be one, self-selected calendar quarter of CY 2019 data. We are proposing that eligible hospitals and CAHs participating in only the EHR Program, or participating in both the Promoting Interoperability Programs and the Hospital IQR Program, report on at least 4 self-selected CQMs. We are also proposing to remove eight CQMs beginning in 2020. We believe to report on the 4 self-selected CQMs electronically would cost ($39.86 × 40 min) 1,594.4 per hospital times 3,300 hospitals results in a total burden of $5,261,520 for all eligible hospitals and CAHs.

In section VIII.D.10. of the preamble of this proposed rule, we are proposing to incorporate into our regulations program guidance regarding subsection (d) Puerto Rico hospitals. Because we are not proposing any new requirements, we do not believe that these proposals will affect burden.

In section VIII.D.12.a. of the preamble of this proposed rule, we are proposing to amend 45 CFR 495.324(b)(2) and 495.324(b)(3) to align with current prior approval policy for MMIS and ADP systems at 45 CFR 95.611(a)(2)(ii), and (b)(2)(iii) and (iv), and to minimize burden on States. Specifically, we are proposing that the prior approval dollar threshold in § 495.324(b)(3) would be increased to $500,000, and that a prior approval threshold of $500,000 would be added to § 495.324(b)(2). In addition, in light of these proposed changes, we are proposing a conforming amendment to amend the threshold in § 495.324(d) for prior approval of justifications for sole source acquisitions to be the same $500,000 threshold. That threshold is currently aligned with the $100,000 threshold in current § 495.324(b)(3). Amending § 495.324(d) to preserve alignment with § 495.324(b)(3) would reduce burden on States and maintain the consistency of our prior approval requirements. We believe that this proposal would reduce burden on States by raising the prior approval thresholds and generally aligning them with the thresholds for prior approval of MMIS and ADP acquisitions costs.

In section VIII.D.12.b. of the preamble of this proposed rule, we are proposing that the 90 percent FFP for Medicaid Promoting Interoperability Program administration would no longer be available for most State expenditures incurred after September 30, 2022. We are proposing a later sunset date, September 30, 2023, for the availability of 90 percent enhanced match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. States would not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023. We do not believe that these proposals would impose any

[402] *https://www.bls.gov/oes/current/oes231011.htm.*

additional burdens on States, because they only affect the timing of State expenditures.

We are requesting public comments on these information collection and recordkeeping requirements.

10. ICRs for Proposed Revisions to the Supporting Documentation Requirements for Medicare Cost Reports

In section IX.B.1. of the preamble of this proposed rule, we are proposing to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339 (OMB No. 0938–0301) into the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS–216 (OMB No. 0938–0102), which would complete our incorporation of the Form CMS–339 into all Medicare cost reports. We also are proposing to update § 413.24(f)(5)(i) to reflect that an acceptable cost report would no longer require the provider to separately submit a Provider Cost Reimbursement Questionnaire, Form CMS–339, by removing the reference to the questionnaire.

There are 58 OPOs and 47 histocompatibility laboratories. This proposal would not require additional data collection from OPOs or histocompatibility laboratories. This proposal would benefit OPOs and histocompatibility laboratories because they would no longer be required to complete and submit the Form CMS–339 as a separate form independent of the Medicare cost report in order to have an acceptable cost report submission under § 413.24(f)(5)(i).

Currently, all OPOs and histocompatibility laboratories are required to complete Form CMS–339. The proposal to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339, into the OPO and Histocompatibility Laboratory cost report would eliminate the requirement to complete the Form CMS–339. The estimated annual burden associated with Form CMS–339 is 3 hours per respondent. The time required by an OPO or a histocompatibility laboratory to complete the Form CMS–339 would be reduced if it is incorporated into the cost report. The incorporation of the Form CMS–339 into the cost report as a cost report worksheet would decrease burden upon OPOs and histocompatibility laboratories. These entities would no longer be required to review multiple pages of questions not applicable to them. This proposal would result in an overall burden reduction to the 58 OPOs and 47 histocompatibility laboratories of a total of 289 hours.

Instead, these entities would be required to respond to 5 questions, which we estimate would take 15 minutes per entity. The total estimated burden across all respondents would be 26 hours ((105 respondents) × (0.25 hours/response)). By eliminating the requirement to complete the inapplicable parts of the Form CMS–339, each OPO or histocompatibility laboratory would experience a net burden decrease of 2.75 hours.

Based on the most recent Bureau of Labor Statistics (BLS) 2016 Occupational Outlook Handbook, the mean hourly wage for Category 43–3031 (bookkeeping, accounting, and auditing clerk) is $19.34. We added 100 percent of the mean hourly wage to account for fringe benefits and overhead, which calculates to a total hourly wage of $38.68 ($19.34 + $19.34). The overall decrease in costs to the 58 OPOs and 47 histocompatibility laboratories is $11,178.52 ($38.68 × 289 hours).

In section IX.B.6. of the preamble of this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, in order for a provider claiming costs on its cost report that are allocated from a home office or chain organization to have an acceptable cost report submission under § 413.24(f)(5), a Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report must be submitted as a supporting document with the provider's cost report. With our proposal, we anticipate that more providers claiming costs on their cost reports that are allocated from a home office or chain organization will submit a Home Office Cost Statement with their cost reports in order to have an acceptable cost report submission. Based on the most recent available FY 2016 data in CMS' System for Tracking Audit and Reimbursement, there were approximately 94 providers that claimed costs on their cost reports that were allocated from approximately 13 home offices or chain organizations, but did not submit a Home Office Cost Statement with their cost reports to substantiate these allocated costs.

Because the existing burden estimate for a provider's cost report already reflects the requirement that providers collect, maintain, and submit this data, there is no additional burden placed upon providers as a result of our proposal to require them to submit these supporting documents along with their cost report in order to have an acceptable cost report submission. To account for the anticipated increase in home office cost statement submissions, we will adjust the number of respondents in the Home Office Cost Statement (OMB Control number 0938–0202) information collection request that is currently being developed for reinstatement.

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.

List of Subjects

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 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this proposed rule, the Centers for Medicare and Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh); secs. 123 and 124 of subtitle A of Title I of Pub. L. 106–113 (113 Stat. 1501A–332); sec. 307 of Subtitle A of Title III of Pub. L. 106–554; sec. 114 of 110–173; sec. 4302 of Pub. L. 111–5; secs. 3106 and 10312 of Pub. L. 111–148; sec. 1206 of Pub. L. 113–67; sec. 112 of Pub. L. 113–93; sec. 231 of Pub. L.

114–113; secs. 15004, 15006, 15007, 15008, 15009, and 15010 of Pub. L. 114–255; and sec. 51005 of Division E of Title X of Pub. L. 115–123.

■ 2. Section 412.3 is amended by revising paragraph (a) to read as follows:

§ 412.3 Admissions.

(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. In addition, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622.

* * * * *

■ 3. Section 412.4 is amended by adding paragraph (c)(4) to read as follows:

§ 412.4 Discharges and transfers.

* * * * *

(c) * * *

(4) For discharges occurring on or after October 1, 2018, to hospice care by a hospice program.

* * * * *

■ 4. Section 412.22 is amended by adding paragraph (h)(2)(iii)(A)(*4*) to read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(h) * * *

(2) * * *

(iii) * * *

(A) * * *

(*4*) On or after October 1, 2018, a satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that provides inpatient services in a building also used by another hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1), is not required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(*1*) through (*3*) of this section in order to be excluded from the inpatient prospective payment system. A satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) which is located in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), is required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(*1*) through (*3*) of this section in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

* * * * *

■ 5. Section 412.25 is amended by—

■ a. Revising paragraphs (a)(1)(ii), (d), and (e)(2)(iii)(A); and

■ b. Adding paragraph (e)(2)(iv).

The revisions and addition read as follows:

§ 412.25 Excluded hospital units: Common requirements.

(a) * * *

(1) * * *

(ii) Prior to October 1, 2019, is not excluded in its entirety from the prospective payment systems; and

* * * * *

(d) *Number of excluded units.* Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems specified in § 412.1(a)(1). A hospital excluded from the prospective payment systems as specified in § 412.1(a)(1) may not have an excluded unit (psychiatric or rehabilitation) that is excluded on the same basis as the hospital.

(e) * * *

(2) * * *

(iii) * * *

(A) Except as provided in paragraph (e)(2)(iv) of this section, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

(iv) Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1).

* * * * *

■ 6. Section 412.64 is amended by revising paragraphs (d)(1)(vii) and (d)(3) to read as follows:

§ § 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vii) For fiscal years 2017, 2018, and 2019, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

* * * * *

(3)(i) Beginning fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal year 2015, by 33 1/3 percent;

(B) For fiscal year 2016, by 66 2/3 percent; and

(C) For fiscal year 2017 and subsequent fiscal years, by 100 percent.

(ii) Beginning fiscal year 2022, in the case of a ''subsection (d) Puerto Rico hospital,'' as defined under section 1886(d)(9)(A) of the Act, that is not a meaningful EHR user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal year 2022, by 33 1/3 percent;

(B) For fiscal year 2023, by 66 2/3 percent; and

(C) For fiscal year 2024 and subsequent fiscal years, by 100 percent.

* * * * *

■ 7. Section 412.90 is amended by revising paragraph (j) to read as follows:

§ 412.90 General rules.

* * * * *

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods

beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before October 1, 2022, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

* * * * *

§ 412.92 [Amended]

■ 8. Section 412.92 is amended—

■ a. In paragraph (a)(1)(ii) by removing the term ''intermediary'' and adding the term ''MAC'' is its place;

■ b. By adding paragraph (a)(4);

■ c. In paragraph (b)(1)(i) by removing the term ''fiscal intermediary'' and adding the term ''MAC'' in its place;

■ d. In paragraphs (b)(1)(iii)(B) and ((b)(1)(iv) by removing the term ''intermediary'' and adding the term ''MAC'' in its place;

■ e. In paragraph (b)(1)(v) by removing the term ''intermediary's'' and adding the term ''MAC's'' in its place, and removing the term ''intermediary'' and adding the term ''MAC'' in its place;

■ f. By revising paragraphs (b)(2)(i) and (ii) introductory text and (b)(2)(ii)(B);

■ g. By adding paragraph (b)(2)(ii)(C);

■ h. By revising paragraph (b)(2)(iv);

■ i. In paragraphs (b)(3)(i), (ii) and (iii) by removing the term ''fiscal intermediary'' and adding the term ''MAC'' in its place;

■ j. In paragraph (b)(3)(iv) by removing the phrase ''fiscal intermediary or'';

■ k. In paragraph (d)(2) introductory text, (e)(1) and (e)(3) introductory text by removing the term ''intermediary'' wherever it appears and adding the term ''MAC'' in its place;

■ l. In paragraph (e)(2) introductory text by removing the term ''intermediary's'' and adding the term ''MAC's'' in its place;

■ m. In paragraph (e)(2)(i) by removing the term ''intermediary'' and adding the term ''MAC'' in its place; and

■ n. In paragraphs (e)(3)(i) introductory text, and (e)(3)(ii) and (iii) by removing the term ''intermediary'' and adding the term ''MAC'' in its place.

The revisions and addition read as follows:

§ 412.92 Special treatment: sole community hospitals.

(a) * * *

(4) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (a)(1)(i) and (ii) of this section are met. For the mileage and rural location criteria in paragraph (a) of this section and the mileage, accessibility, and travel time criteria specified in paragraphs (a)(1) through (3) of this section, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

(b) * * *

(2) * * *

(i) For applications received on or before September 30, 2018, sole community hospital status is effective 30 days after the date of CMS' written notification of approval, except as provided in paragraph (b)(2)(v) of this section. For applications received on or after October 1, 2018, sole community hospital status is effective as of the date CMS receives the complete application, except as provided in paragraph (b)(2)(v) of this section.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses a CMS denial of sole community hospital status and no further appeal is made, the sole community hospital status is effective as follows:

* * * * *

(B) If the hospital's application for sole community hospital status was received on or after October 1, 1983 and on or before September 30, 2018, the effective date is 30 days after the date of CMS' original written notification of denial.

(C) If the hospital's application for sole community hospital status was received on or after October 1, 2018, the effective date is the date CMS receives the complete application.

* * * * *

(iv) For applications received on or before September 30, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification. For applications received on or after October 1, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after the date CMS receives the complete application.

* * * * *

■ 9. Section 412.96 is amended by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(d) *Criteria for hospitals that have remote location(s).* For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (b)(1) and (2) and (c)(1) through (5) of this section are met. For the rural location criteria specified in paragraphs (b)(1) and (c) of this section and the mileage criteria specified in paragraphs (b)(2)(ii) and (c)(4) of this section, the hospital must demonstrate that the main campus and its remote locations each independently satisfy those requirements.

* * * * *

■ 10. Section 412.101 is amended by—

■ a. Revising paragraph (b)(2);

■ b. Revising paragraphs (c)(1) and (2) introductory text;

■ c. Adding paragraph (c)(3); and

■ d. Revising paragraph (d).

The revisions and addition read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(b) * * *

(2) In order to qualify for this adjustment, a hospital must meet the following criteria, subject to the provisions of paragraph (e) of this section:

(i) For FY 2005 through FY 2010 and FY 2023 and subsequent fiscal years, a hospital must have fewer than 200 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 25 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(ii) For FY 2011 through FY 2018, a hospital must have fewer than 1,600 Medicare discharges, as defined in paragraph (a) of this section, during the

fiscal year, based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS, and be located more than 15 road miles, as defined in paragraph (a) of this section, from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(iii) For FY 2019 through FY 2022, a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 15 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

* * * * *

(c) * * *

(1) For FY 2005 through FY 2010 and FY 2023 and subsequent fiscal years, the adjustment is an additional 25 percent for each Medicare discharge.

(2) For FY 2011 through FY 2018, the adjustment is as follows:

* * * * *

(3) For FY 2019 through FY 2022, the adjustment is as follows:

(i) For low-volume hospitals with 500 or fewer total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, the adjustment is an additional 25 percent for each Medicare discharge.

(ii) For low-volume hospitals with more than 500 and fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(95/330)—(number of total discharges/13,200)]. ''Total discharges'' is determined as described in paragraph (b)(2)(iii) of this section.

(d) *Eligibility of new hospitals for the adjustment.* For FYs 2005 through 2010 and FY 2019 and subsequent fiscal years, a new hospital will be eligible for a low-volume adjustment under this section once it has submitted a cost report for a cost reporting period that indicates that it meets discharge requirements during the applicable fiscal year and has provided its Medicare administrative contractor with sufficient evidence that it meets the distance requirement, as specified in paragraph (b)(2) of this section.

* * * * *

■ 11. Section 412.103 is amended by adding paragraph (a)(7) and revising paragraph (b)(6) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(7) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, the hospital is required to demonstrate that the main campus and its remote location(s) each independently satisfy the location conditions specified in paragraphs (a)(1), (2), and (6) of this section.

(b) * * *

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (2), and (4) and (h) for the 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 this section no later than 60 days after the public display date at the Office of the Federal Register of the inpatient prospective payment system proposed rule for the next Federal fiscal year.

* * * * *

§ 412.105 [Amended]

■ 12. Section 412.105 is amended in paragraph (f)(1)(vii) by removing the reference ''§§ 413.79(e)(1) through (e)(4)'' and adding in its place the reference ''§ 413.79(e)''.

■ 13. Section 412.106 is amended by adding paragraph (g)(1)(iii)(C)(*5*) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*5*) For fiscal year 2019, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (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), and for hospitals other than Puerto Rico hospitals, IHS or Tribal hospitals, and all-inclusive rate providers, data on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs from 2014 and 2015 cost reports from the most recent HCRIS database extract.

* * * * *

§ 412.108 [Amended]

■ 14. Section 412.108 is amended—

■ a. By revising paragraph (a)(1);

■ b. By adding paragraph (a)(3);

■ c. By revising paragraph (b)(4) introductory text;

■ d. In paragraphs (b)(1) and (3), and (b)(4)(i), (ii), and (iii), (b)(5), (6), (7), (8), and (9), and (d)(1), (d)(2)(i), (d)(3) introductory text, and (d)(3)(i), (ii), and (iii) by removing the terms ''fiscal intermediary'' and ''intermediary'' wherever they appear and adding the term ''MAC'' in their place;

■ e. In paragraph (b)(8) and (9) and (d)(2) introductory text by removing the terms ''fiscal intermediary's'' and ''intermediary's'' and adding the term ''MAC's'' in their place; and

■ f. By revising paragraph (c)(2)(iii) introductory text.

The revisions and additions read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

(a) * * *

(1) *General considerations.* For cost reporting periods beginning on or after April 1, 1990, and ending before October 1, 1994, or for discharges occurring on or after October 1, 1997, and before October 1, 2022, a hospital is classified as a Medicare-dependent, small rural hospital if it meets all of the following conditions:

(i) It is located in a rural area (as defined in subpart D of this part) or it is located in a State with no rural area and satisfies any of the criteria under § 412.103(a)(1) or (3) or under § 412.103(a)(2) as of January 1, 2018.

(ii) The hospital has 100 or fewer beds as defined in § 412.105(b) during the cost reporting period.

(iii) The hospital is not also classified as a sole community hospital under § 412.92.

(iv) At least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the hospital's cost reporting period or periods as follows, subject to the provisions of paragraph (a)(1)(v) of this section:

(A) The hospital's cost reporting period ending on or after September 30, 1987 and before September 30, 1988.

(B) If the hospital does not have a cost reporting period that meets the criterion set forth in paragraph (a)(1)(iv)(A) of this section, the hospital's cost reporting period beginning on or after October 1, 1986, and before October 1, 1987.

(C) At least two of the last three most recent audited cost reporting periods for which the Secretary has a settled cost report.

(v) If the cost reporting period determined under paragraph (a)(1)(iv) of this section is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

* * * * *

(3) *Criteria for hospitals that have remote location(s).* For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria in paragraphs (a)(1) and (2) of this section are met. For the location requirement specified in paragraph (a)(1)(i) of this section, the hospital must demonstrate that the main campus and its remote locations each independently satisfy this requirement.

(b) * * *

(4) For applications received on or before September 30, 2018, a determination of MDH status made by the MAC is effective 30 days after the date the MAC provides written notification to the hospital. For applications received on or after October 1, 2018, a determination of MDH status made by the MAC is effective as of the date CMS receives the complete application. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

* * * * *

(c) * * *

(2) * * *

(iii) For discharges occurring during cost reporting periods (or portions thereof) beginning on or after October 1, 2006, and before October 1, 2022, 75 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the highest of the following:

* * * * *

■ 15. Section 412.152 is amended by adding, in alphabetical order, definitions of ''Applicable period for dual-eligibility'', ''Dual-eligible'', and ''Proportion of dual-eligibles'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Applicable period for dual-eligibility is the 3-year data period corresponding to the applicable period as established by the Secretary for the Hospital Readmissions Reduction Program.

* * * * *

Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged from the hospital.

* * * * *

Proportion of dual-eligibles is the number of dual-eligible patients among all Medicare Fee-for-Service and Medicare Advantage stays during the applicable period.

* * * * *

■ 16. Section 412.164 is amended by revising paragraph (a) to read as follows:

§ 412.164 Measure selection under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will select measures, other than measures of readmissions, for purposes of the Hospital VBP Program. The measures will be selected from the measures specified under section 1886(b)(3)(B)(viii) of the Act (the Hospital Inpatient Quality Reporting Program).

* * * * *

■ 17. Section 412.200 is revised to read as follows:

§ 412.200 General provisions.

Beginning with discharges occurring on or after October 1, 1987, hospitals located in Puerto Rico are subject to the rules governing the prospective payment system for inpatient operating costs. Except as provided in this subpart, the provisions of subparts A, B, C, F, G, and H of this part apply to hospitals located in Puerto Rico. Except for § 412.60, which deals with DRG classification and weighting factors, or as otherwise specified, the provisions of subparts D and E, which describe the methodology used to determine prospective payment rates for inpatient operating costs for hospitals, do not apply to hospitals located in Puerto Rico. Instead, the methodology for determining prospective payment rates for inpatient operating costs for these hospitals is set forth in §§ 412.204 through 412.212.

■ 18. Section 412.230 is amended by revising paragraph (d)(5) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(d) * * *

(5) *Single hospital MSA exception.* The requirements of paragraph (d)(1)(iii) of this section do not apply if a hospital is the single hospital in its MSA with published 3-year average hourly wage data included in the current fiscal year inpatient prospective payment system final rule.

■ 19. Section 412.500 is amended by adding paragraphs (a)(9) and (10) to read as follows:

§ 412.500 Basis and scope of subpart.

(a) * * *

(9) Section 51005(a) of Public Law 115–123 which extended the blended payment rate for the site neutral payment rate cases to apply to discharges occurring in cost reporting periods beginning in FYs 2018 and 2019.

(10) Section 51005(b) of Public Law which reduces the IPPS comparable amount for the site neutral payment rate cases by 4.6 percent for FYs 2018 through 2026.

* * * * *

■ 20. Section 412.522 is amended by—

■ a. Adding paragraph (c)(1)(iii);

■ b. Removing paragraph (c)(2)(v); and

■ c. Revising paragraph (c)(3) introductory text.

The addition and revision read as follows:

§ 412.522 Application of site neutral payment rate.

* * * * *

(c) * * *

(1) * * *

(iii) For discharges occurring in fiscal years 2018 through 2026, the amount in paragraph (c)(1)(i) of this section is reduced by 4.6 percent.

* * * * *

(3) *Transition.* For discharges occurring in cost reporting periods beginning on or after October 1, 2015 and on or before September 30, 2019, payment for discharges under paragraph (c)(1) of this section are made using a blended payment rate, which is determined as—

* * * * *

■ 21. Section 412.523 is amended by adding paragraphs (c)(3)(xv) and (d)(6) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xv) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2018, and ending September 30, 2019.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2018, and ending September 30, 2019, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.15 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(6) *Adjustment for the elimination of the limitation on long-term care hospital admissions from referring hospitals.* The standard Federal payment rate determined in paragraph (c)(3) of this section for discharges occurring on or after October 1, 2018 is permanently adjusted by a one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2019 are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals.

* * * * *

§ 412.525 [Amended]

■ 22. Section 412.525 is amended by removing paragraph (d)(6).

§ 412.538 [Removed and reserved]

■ 23. Section 412.538 is removed and reserved.

■ 24. Section 412.560 is amended by—

■ a. Adding paragraph (b)(3); and

■ b. Revising paragraphs (d)(1) and (3).

The addition and revisions read as follows:

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

* * * * *

(b) * * *

(3) CMS may remove a quality measure from the LTCH QRP based on one or more of the following factors:

(i) Measure performance among long-term care hospitals is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better patient outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.

(v) A measure that is more proximal in time to desired patient outcomes for the particular topic is available.

(vi) A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

(vii) Collection or public reporting of a measure leads to negative, unintended consequences other than patient harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

* * * * *

(d) * * *

(1) *Written letter of noncompliance decision.* Long-term care hospitals that do not meet the requirement in paragraph (b) of this section for a program year will receive a notification of noncompliance sent through at least one of the following methods: Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system, the United States Postal Service, or via an email from the MAC.

* * * * *

(3) *CMS decision on reconsideration request.* CMS will notify long-term care hospitals, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: The QIES ASAP system, the United States Postal Service, or via an email from the MAC.

* * * * *

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

■ 25. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 26. Section 413.24 is amended by revising paragraph (f)(5)(i) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(5) * * *

(i) All providers—The provider must accurately complete and submit the required cost reporting forms, including all necessary signatures and supporting documents. A cost report is rejected for lack of supporting documentation if it does not include the following:

(A) *Teaching hospitals*—For teaching hospitals, the Intern and Resident Information System (IRIS) data. Effective for cost reports filed on or after October 1, 2018, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the provider's cost report.

(B) *Bad debt*—Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a detailed bad debt listing that corresponds to the amount of bad debt claimed in the provider's cost report.

(C) *DSH eligible hospitals*—Effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a disproportionate share hospital payment adjustment, a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. If the hospital submits an amended cost report that changes its Medicaid eligible days, the hospital must submit an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report.

(D) *Charity care and uninsured discounts*—Effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the DSH eligible hospital's cost report.

(E) *Home office cost allocation*—Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization, a home office cost statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report.

* * * * *

■ 27. Section 413.79 is amended by revising paragraph (e)(1)(iv) to read as follows:

§ 413.79 Direct GME Payments: Determination of the weighted number of FTE residents.

* * * * *

(e) * * *

(1) * * *

(iv)(A) Effective for Medicare GME affiliation agreements entered into on or after October 1, 2005, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(B) Effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap only if the decrease results from a Medicare GME affiliated group consisting solely of two or more urban hospitals that qualify to receive adjustments to their FTE caps under paragraph (e)(1) of this section.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 28. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 29. Section 424.11 is amended by revising paragraphs (b) and (c) to read as follows:

§ 424.11 General procedures.

* * * * *

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification. If supporting information for the signed statement is contained in other provider records (such as physicians' progress notes), it need not be repeated in the statement itself.

(c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 30. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 31. Section 495.4 is amended—

■ a. In the definition of ''EHR reporting period'' by revising paragraph (1)(iii), adding paragraph (1)(iv), revising paragraphs (2)(ii)(C) and (D) and (2)(iii), and adding paragraph (2)(iv);

■ b. In the definition of ''EHR reporting period for a payment adjustment year'' by revising paragraph (2)(iii) and adding paragraph (2)(iv), revising paragraph (3)(iii), and adding paragraph (3)(iv); and

■ c. By revising the definitions of ''Payment adjustment year'' and ''Payment year''.

The revisions and additions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(iii) For the CY 2019 payment year under the Medicaid Promoting Interoperability Program:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2019.

(B) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2019.

(iv) For the CY 2020 payment year under the Medicaid Promoting Interoperability Program:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2020.

(B) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2020.

(2) * * *

(ii) * * *

(C) For the FY 2017 payment year as follows:

(*1*) Under the Medicaid EHR Incentive Program:

(*i*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2017.

(*ii*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2017.

(*iii*) For the eligible hospital or CAH demonstrating the Stage 3 objectives and measures at § 495.24, any continuous 90-day period within CY 2017.

(*2*) Under the Medicare EHR Incentive Program, for a Puerto Rico eligible hospital, any continuous 14-day period within CY 2017.

(D) For the FY 2018 payment year as follows:

(*1*) Under the Medicaid Promoting Interoperability Program:

(*i*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2018.

(*ii*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2018.

(*2*) Under the Medicare Promoting Interoperability Program, for a Puerto Rico eligible hospital, any continuous 90-day period within CY 2018.

(iii) For the FY 2019 payment year as follows:

(A) Under the Medicaid Promoting Interoperability Program:

(*1*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2019.

(*2*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2019.

(B) Under the Medicare Promoting Interoperability Program, for a Puerto Rico eligible hospital, any continuous 90-day period within CY 2019.

(iv) For the FY 2020 payment year as follows:

(A) Under the Medicaid Promoting Interoperability Program:

(*1*) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2020.

(*2*) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2020.

(B) Under the Medicare Promoting Interoperability Program, for a Puerto

Rico eligible hospital, any continuous 90-day period within CY 2020.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(iii) The following are applicable for 2019:

(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 2019 and applies for the FY 2020 and 2021 payment adjustment years. For the FY 2020 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, 2019.

(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 2019 and applies for the FY 2021 payment adjustment year.

(iv) The following are applicable for 2020:

(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 2020 and applies for the FY 2021 and 2022 payment adjustment years. For the FY 2021 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, 2020.

(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 2020 and applies for the FY 2022 payment adjustment year.

(3) * * *

(iii) The following are applicable for 2019:

(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 2019 and applies for the FY 2019 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 2019 and applies for the FY 2019 payment adjustment year.

(iv) The following are applicable for 2020:

(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 2020 and applies for the FY 2020 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 2020 and applies for the FY 2020 payment adjustment year.

* * * * *

Payment adjustment year means the following:

(1) For an EP, a calendar year beginning with CY 2015.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2015.

(3) For a Puerto Rico eligible hospital, a Federal fiscal year beginning with FY 2022.

Payment year means the following:

(1) For an EP, a calendar year beginning with CY 2011.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2011.

(3) For a Puerto Rico eligible hospital, a Federal fiscal year beginning with FY 2016.

* * * * *

■ 32. Section 495.24 is amended by revising the introductory text, paragraphs (c) and (d) headings and adding paragraph (e) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

The criteria specified in paragraphs (c) and (d) of this section are optional for 2017 and 2018 for EPs, eligible hospitals, and CAHs that have successfully demonstrated meaningful use in a prior year. The criteria specified in paragraph (d) of this section are applicable for all EPs for 2019 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting Interoperability Program for 2019 and subsequent years. The criteria specified in paragraph (e) of this section are applicable for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years.

* * * * *

(c) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS—*

* * * * *

(d) *Stage 3 objectives and measures for all EPs for 2019 and subsequent years, and for eligible hospitals and CAHs attesting to a State for the Medicaid Promoting Interoperability Program for 2019 and subsequent years—*

* * * * *

(e) *Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 2019 and subsequent years—*

(1) *General rule.* Except as specified in paragraph (e)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in this paragraph (e) and earn a total score of at least 50 points to meet the definition of a meaningful EHR user.

(2) *Exclusion for nonapplicable measures.* (i) An eligible hospital or CAH may exclude a particular measure that includes an option for exclusion contained in this paragraph (e) if the eligible hospital or CAH meets the following requirements:

(A) Meets the criteria in the applicable measure that would permit the exclusion.

(B) Attests to the exclusion.

(ii) *Distribution of points for nonapplicable measures.* For eligible hospitals or CAHs that claim such exclusion, the points assigned to the excluded measure will be distributed to other measures as outlined in this paragraph (e).

(3) *Objectives and associated measures in this paragraph (e) that rely on measures that count unique patients or actions.* (i) If a measure (or associated objective) in this paragraph (e) references paragraph (e)(3) of this section, the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data were entered in the CEHRT to allow the record to be saved, and not rejected due to incomplete data.

(ii) If the objective and associated measure does not reference this paragraph (e)(3), the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(4) *Protect patient health information*—(i) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(ii) *Measure scoring.* Eligible hospitals and CAHs are required to report on the security risk analysis measure in paragraph (e)(4)(iii) of this section, but no points are available for this measure.

(iii) *Security risk analysis measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45

CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(5) *Electronic prescribing*—(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *Measures scoring.* (A) In 2019, eligible hospitals and CAHs must meet the e-Prescribing measure in paragraph (e)(5)(iii)(A) of this section and have the option to report on the query of PDMP measure and verify opioid treatment agreement measure in paragraphs (e)(5)(iii)(B) and (C) of this section. The electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 20 points.

(B) In 2020 and subsequent years, eligible hospitals and CAHs must meet each of the measures in paragraphs (e)(5)(iii)(A), (B) and (C) of this section. The electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 15 points.

(iii) *Measures.* (A) *e-Prescribing measure.* Subject to paragraph (e)(3) of this section, at least one hospital discharge medication order for permissible prescriptions (for new and changed prescriptions) is queried for a drug formulary and transmitted electronically using CEHRT. This performance-based measure is worth up to 10 points in 2019 and up to 5 points in 2020 and subsequent years.

(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 performance-based measure is worth up to 5 bonus points in 2019 and up to 5 points in 2020 and subsequent years.

(C) *Verify opioid treatment agreement measure.* Subject to paragraph (e)(4) of this section, f or at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month look-back period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's electronic health record using CEHRT. This performance-based measure is worth up to 5 bonus points in 2019 and up to 5 points in 2020 and subsequent years.

(iv) *Exclusion for an EHR reporting period in CY 2019 in accordance with paragraph (e)(2) of this section.* An exclusion claimed under paragraph (e)(5)(vi)(A) of this section will redistribute 10 points equally among the measures associated with the health information exchange objective under paragraph (e)(6) of this section.

(v) *Exclusions beginning with an EHR reporting period in CY 2020 in accordance with paragraph (e)(2) of this section.* An exclusion claimed under paragraph (e)(5)(vi)(A) of this section will redistribute 15 points equally among the measures associated with the health information exchange objective under paragraph (e)(6) of this section and the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section. An exclusion claimed under paragraph (e)(5)(vi)(B) or (C) of this section will redistribute 5 points for each excluded measure to the e-Prescribing measure under paragraph (e)(5)(iii)(A) of this section.

(vi) *Exclusions in accordance with paragraph (e)(2) of this section.* (A) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period may be excluded from the measure specified in paragraph (e)(5)(iii)(A) of this section for an EHR reporting period in CY 2019 and may be excluded from the measures specified in paragraphs (e)(5)(iii)(A) through (C) of this section beginning with an EHR reporting period in CY 2020.

(B) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period may be excluded from the measures specified in paragraphs (e)(5)(iii)(B) and (C) of this section beginning with an EHR reporting period in CY 2020.

(C) Any eligible hospital or CAH that is unable to report the measure in accordance with applicable law may be excluded from the measures specified in paragraphs (e)(5)(iii)(B) and (C) of this section beginning with an EHR reporting period in CY 2020.

(6) *Health information exchange*—(i) *Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(ii) *Measures.* Eligible hospitals and CAHs must meet both of the following measures (each worth up to 20 points), and could receive up to 40 points for this objective.

(A) *Support electronic referral loops by sending health information measure:* Subject to paragraph (e)(3) of this section, for at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(*1*) Creates a summary of care record using CEHRT; and

(*2*) Electronically exchanges the summary of care record.

(B) *Support electronic referral loops by receiving and incorporating health information measure:* Subject to paragraph (e)(3) of this section, for at least one electronic summary of care record received for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, mediation allergy, and current problem list.

(iii) *Exclusions in accordance with paragraph (e)(2) of this section.* Claiming the exclusion will redistribute 20 points to the support electronic referral loops by sending health information measure under paragraph (e)(6)(ii)(A). Any eligible hospital or CAH that is unable to implement the measure for an EHR reporting period in 2019 may be excluded from the measure specified in paragraph (e)(6)(ii)(B) of this section.

(7) *Provider to Patient Exchange*—(i) *Objective.* The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information.

(ii) *Provide patients electronic access to their health information measure.* Eligible hospitals and CAHs must meet the following measure, and could receive up to 40 points for this objective in 2019 and up to 35 points for this objective in 2020 and subsequent years.

For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23)—

(A) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(B) The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT. This performance-based measure is worth up to 40 points in 2019 and up to 35 points in 2020 and subsequent years.

(8) *Public health and clinical data exchange*—(i) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measures.* In order to meet the objective under paragraph (e)(8)(i) of this section, an eligible hospital or CAH must meet the syndromic surveillance reporting measure in paragraph (e)(8)(ii)(A) of this section and one additional measure from paragraphs (e)(8)(ii)(B) through (F) of this section. Eligible hospitals and CAHs could receive a total of 10 points for this objective.

(A) *Syndromic surveillance reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.

(B) *Immunization registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(C) *Electronic case reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(D) *Public health registry reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(E) *Clinical data registry reporting measure.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(F) *Electronic reportable laboratory result reporting measure.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(iii) *Exclusions in accordance with paragraph (e)(2) of this section.* An exclusion claimed under paragraphs (e)(8)(iii)(A) through (F) of this section will redistribute 10 points to the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section.

(A) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (e)(8)(ii)(A) of this section if the eligible hospital or CAH—

(*1*) Does not have an emergency or urgent care department.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

(B) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from to the immunization registry reporting measure specified in paragraph (e)(8)(ii)(B) of this section if the eligible hospital or CAH—

(*1*) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.

(C) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic case reporting measure specified in paragraph (e)(8)(ii)(C) of this section if the eligible hospital or CAH—

(*1*) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.

(D) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (e)(8)(ii)(D) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(E) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (e)(8)(ii)(E) of this section if the eligible hospital or CAH—

(*1*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(F) Any eligible hospital or CAH meeting one or more of the following

criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (e)(8)(ii)(F) of this section if the eligible hospital or CAH—

(*1*) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(*2*) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*3*) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

■ 33. Section 495.40 is amended by adding paragraph (b)(2)(vii) to read as follows:

§ 495.40 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(vii) *Exception for dual-eligible eligible hospitals and CAHs beginning in CY 2019.* (A) Beginning with the EHR reporting period in CY 2019, dual-eligible eligible hospitals and CAHs (those that are eligible for an incentive payment under Medicare for meaningful use of CEHRT and/or subject to the Medicare payment reduction for failing to demonstrate meaningful use, and are also eligible to earn a Medicaid incentive payment for meaningful use) must satisfy the requirements under paragraph (b)(2) of this section by attestation and reporting information to CMS, not to their respective state Medicaid agency.

(B) Dual-eligible eligible hospitals and CAHs that demonstrate meaningful use to their state Medicaid agency may only qualify for an incentive payment under Medicaid and will not qualify for an incentive payment under Medicare and/or avoid the Medicare payment reduction.

* * * * *

■ 34. Section 495.100 is amended by revising the definition of ''Eligible hospital'' and adding a definition of ''Puerto Rico eligible hospital'' in alphabetical order to read as follows:

§ 495.100 Definitions.

* * * * *

Eligible hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter, excluding those hospitals specified in § 412.23 of this chapter, excluding those hospital units specified in § 412.25 of this chapter, and including Puerto Rico eligible hospitals unless otherwise indicated.

* * * * *

Puerto Rico eligible hospital means a subsection (d) Puerto Rico hospital as defined in section 1886(d)(9)(A) of the Social Security Act.

* * * * *

■ 35. Section 495.104 is amended by adding paragraphs (b)(6) through (10) and (c)(5)(vi) through (x) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(b) * * *

(6) Puerto Rico eligible hospitals whose first payment year is FY 2016 may receive such payments for FYs 2016 through 2019.

(7) Puerto Rico eligible hospitals whose first payment year is FY 2017 may receive such payments for FYs 2017 through 2020.

(8) Puerto Rico eligible hospitals whose first payment year is FY 2018 may receive such payments for FYs 2018 through 2021.

(9) Puerto Rico eligible hospitals whose first payment year is FY 2019 may receive such payments for FYs 2019 through 2021.

(10) Puerto Rico eligible hospitals whose first payment year is FY 2020 may receive such payments for FYs 2020 through 2021.

(c) * * *

(5) * * *

(vi) For Puerto Rico eligible hospitals whose first payment year is FY 2016—

(A) 1 for FY 2016;

(B) 3/4 for FY 2017;

(C) 1/2 for FY 2018; and

(D) 1/4 for FY 2019.

(vii) For Puerto Rico eligible hospitals whose first payment year is FY 2017—

(A) 1 for FY 2017;

(B) 3/4 for FY 2018;

(C) 1/2 for FY 2019; and

(D) 1/4 for FY 2020;

(viii) For Puerto Rico eligible hospitals whose first payment year is FY 2018—

(A) 1 for FY 2018;

(B) 3/4 for FY 2018;

(C) 1/2 for FY 2019; and

(D) 1/4 for FY 2020.

(ix) For Puerto Rico eligible hospitals whose first payment year is FY 2019—

(A) 3/4 for FY 2019;

(B) 1/2 for FY 2020; and

(C) 1/4 for FY 2021.

(x) For Puerto Rico eligible hospitals whose first payment year is FY 2020—

(A) 1/2 for FY 2020; and

(B) 1/4 for FY 2021.

* * * * *

■ 36. Section 495.200 is amended by revising the definitions of ''MA payment adjustment year'' and ''Payment year'' to read as follows:

§ 495.200 Definitions.

* * * * *

MA payment adjustment year means—

(1) Except as provided in paragraph (2) of this definition, for qualifying MA organizations that receive an MA EHR incentive payment for at least 1 payment year, calendar years beginning with CY 2015.

(2) For qualifying MA organizations that receive an MA EHR incentive payment for a qualifying MA-affiliated eligible hospital in Puerto Rico for at least 1 payment year, and that have not previously received an MA EHR incentive payment for a qualifying MA-affiliated eligible hospital not in Puerto Rico, calendar years beginning with CY 2022.

(3) For MA-affiliated eligible hospitals, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the Federal fiscal year ending in the MA payment adjustment year.

(4) For MA EPs, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the calendar year concurrent with the payment adjustment year.

* * * * *

Payment year means—

(1) For a qualifying MA EP, a calendar year beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year beginning with FY 2011 and ending with FY 2016; and

(3) For an eligible hospital in Puerto Rico, a Federal fiscal year beginning with FY 2016 and ending with FY 2021.

* * * * *

■ 37. Section 495.211 is amended by adding paragraph (e)(4) to read as follows:

§ 495.211 Payment adjustments effective for 2015 and subsequent MA payment years with respect to MA EPs and MA-affiliated eligible hospitals.

* * * * *

(e) * * *

(4) For MA payment adjustment years prior to 2022, subsection (d) Puerto Rico hospitals are neither potentially qualifying MA-affiliated eligible hospitals nor qualifying MA-affiliated eligible hospitals for purposes of

applying the payment adjustments under paragraph (e) of this section.

■ 38. Section 495.316 is amended by revising paragraph (g)(2) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(g) * * *

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013 and ending after 2018.

* * * * *

■ 39. Section 495.322 is revised to read as follows:

§ 495.322 FFP for reasonable administrative expenses.

(a) Subject to prior approval conditions at § 495.324, FFP is available at 90 percent in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers.

(b) FFP available under paragraph (a) of this section is available only for expenditures incurred on or before September 30, 2022, except for expenditures related to audit and appeal activities required under this subpart, which must be incurred on or before September 30, 2023.

■ 40. Section 495.324 is amended by revising paragraphs (b)(2) and (3) and (d) to read as follows:

§ 495.324 Prior approval conditions.

* * * * *

(b) * * *

(2) For the acquisition solicitation documents and any contract that a State may utilize to complete activities under this subpart, unless specifically exempted by the Department of Health and Human Services, prior to release of the acquisition solicitation documents or prior to execution of the contract, when the contract is anticipated to or will exceed $500,000.

(3) For contract amendments, unless specifically exempted by the Department of Health and Human Services, prior to execution of the contract amendment, involving contract cost increases exceeding $500,000 or contract time extensions of more than 60 days.

* * * * *

(d) A State must obtain prior written approval from HHS of its justification for a sole source acquisition, when it plans to acquire noncompetitively from a nongovernmental source HIT equipment or services, with proposed FFP under this subpart if the total State and Federal acquisition cost is more than $500,000.

Dated: March 29, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: April 2, 2018.

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—Proposed Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2018, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2018

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 2019 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 2019. 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, 2018.

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 2019.

In general, except for SCHs and MDHs, for FY 2019, 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. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018, enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

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.

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 2019, 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 below 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 2019. 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 2019. 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 2019. 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 2019. 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 2019

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. Below we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2019.

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 2019, 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 2019 inpatient hospital update. Below is a table with these four options:

FY 2019	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	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.25	−0.85	0.55	−1.55

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 2019.

- 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 2017 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.
- An adjustment to remove the FY 2018 outlier offset and apply an offset for FY 2019, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2019, 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 2019 wage index for the rural floor. We note that, in section III.H.2.b. of the preamble to this proposed rule, we are proposing not to extend the imputed floor policy (both the original methodology and alternative methodology) for FY 2019. Therefore, for FY 2019, in this proposed rule, we are proposing to not include the imputed floor (calculated under the original methodology and alternative methodology) in calculating the uniform, national rural floor budget neutrality adjustment, which is reflected in the proposed FY 2019 wage index.

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 2019, 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 2018. 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 2019, 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 2019 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 2019. 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 2019 applicable percentage increase (which is based on IGI's fourth quarter 2017 forecast of the 2014-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2019) of 0.8 percentage point, which is also calculated based on IGI's fourth quarter 2017 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2019 by the estimated market basket percentage increase less 0.75 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services required as inputs to provide hospital inpatient services.

Based on IGI's 2017 fourth quarter 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 2019 for this proposed rule is 2.8 percent. As discussed earlier, for FY 2019, 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 2019 inpatient hospital update to the standardized amount. We also refer readers to the table above 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 2019 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 2019 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 2019 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we apply 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 2019 standardized amount to remove the effects of the FY 2018 geographic reclassifications and outlier payments before applying the FY 2019 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2019 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.

• For FY 2019, the Bundled Payments for Care Improvement (BPCI) Initiative will have ended and a new model, the BPCI Advanced model will have begun. 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/.*

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI Initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2019, consistent with how we have treated hospitals that participated in the BPCI Initiative, 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.

• 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 2019 and subsequent years, we are proposing to continue to apply a proxy hospital readmissions payment adjustment and a proxy hospital VBP payment adjustment 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 proposed proxy readmissions payment adjustment factor and a proposed proxy hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proposed proxy FY 2019 readmissions payment adjustment factors, for both this proposed rule and the final rule, as discussed in section IV.H. of the preamble of this proposed rule, we are proposing to use the proportion of dually-eligible Medicare beneficiaries, excess readmission ratios, and aggregate payments for excess readmissions from the prior fiscal year's applicable period because, at this time and at the time of the development of the final rule, hospitals will not yet have had the opportunity to review and correct the data (program calculations based on the proposed FY 2019 applicable period of July 1, 2014 to June 30, 2017) before the data are made public under our policy regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400) and section IV.H. of the preamble of this proposed rule.)

In addition, for FY 2019, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 2019 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2019 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

• 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 an 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 2019 (as we did for the last 5 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.F. of the preamble to this proposed rule and below, 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.F. 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 2019. Similar to FY 2018, 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 2019.

• 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.

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 2019, 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 2017 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2018 labor-related share percentages, the FY 2018 relative weights, and the FY 2018 pre-reclassified wage data, and applied the proposed FY 2019 hospital readmissions payment adjustments and estimated FY 2019 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2018 labor-related share percentages, the proposed FY 2019 relative weights, and the FY 2018 pre-reclassified wage data, and applied the proposed FY 2019 hospital readmissions payment adjustments and estimated FY 2019 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.997896 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 of 0.997896 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2018.

b. Updated Wage Index—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 2019, 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 2017 discharge data to simulate payments and compared the following:

• Aggregate payments using the proposed FY 2019 relative weights and the FY 2018 pre-reclassified wage indexes, applied the FY 2018 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 2019 hospital readmissions payment adjustment and the estimated FY 2019 hospital VBP payment adjustment; and

• Aggregate payments using the proposed FY 2019 relative weights and the proposed FY 2019 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2019 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 2019 hospital readmissions payment adjustments and estimated FY 2019 hospital VBP payment adjustments applied above.

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 2018 to FY 2019. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 1.001182 for proposed changes to the wage index.

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 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 proposed budget neutrality adjustment factor for FY 2019, we used FY 2017 discharge data to simulate payments and compared the following:

• Aggregate payments using the proposed FY 2019 labor-related share percentages, the proposed FY 2019 relative weights, and the proposed FY 2019 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 2019 hospital readmissions payment adjustments and the estimated FY 2019 hospital VBP payment adjustments; and

• Aggregate payments using the proposed FY 2019 labor-related share percentages, the proposed FY 2019 relative weights, and the proposed FY 2019 wage data after such reclassifications, and applied the same proposed FY 2019 hospital readmissions payment adjustments and the estimated FY 2019 hospital VBP payment adjustments applied above.

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 2019, and apply the proposed policies explained in section III. of the preamble of this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.987084 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2019 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2018 budget

neutrality adjustment factor. We note that the proposed FY 2019 budget neutrality adjustment reflects FY 2019 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

d. Rural Floor 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.

As noted above and as discussed in section III.G.2. of the preamble of this proposed rule, the imputed floor is set to expire effective October 1, 2018, and we are not proposing to extend the imputed floor policy.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2019, 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 2019 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 2019 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2019 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 2017 discharge data to simulate payments 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 of 0.994733. The national adjustment was applied to the national wage indexes to produce a proposed national rural floor budget neutral wage index.

e. Proposed Rural Community Hospital Demonstration Program Adjustment

In section IV.L. 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 below). 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 the reader to section IV.L. 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 2019, 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 $73,191,887. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2019, we computed a proposed factor of 0.999325 for the Rural Community Hospital Demonstration budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate. We refer readers to section IV.L. 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 amount.

We note, as discussed in section IV.L. of the preamble of this proposed rule, if updated or additional data become available prior to issuance of the FY 2019 IPPS/LTCH PPS final rule, we would use those data to the extent appropriate to determine the budget neutrality offset amount for FY 2019. We refer readers to section IV.L. of the preamble of this proposed rule on complete details regarding the availability of additional data prior to the FY 2019 IPPS/LTCH PPS final rule.

f. Proposed Adjustment for FY 2019 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 2019, we are proposing to implement the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

g. 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 2019 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 5.1 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 FY 2019 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 2019 outlier threshold, we simulated payments by applying proposed FY 2019 payment rates and policies using cases from the FY 2017 MedPAR file. 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 below) 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 2019 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2017 to FY 2019. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57282), we are using the following methodology to calculate the charge inflation factor for FY 2019:

- To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation: 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.
- 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.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49779 through 49780), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. In response to those comments, similar to FY 2016, FY 2017, and FY 2018, for FY 2019, we grouped claims data by quarter in the table below in order that the public would be able to replicate the claims summary for the claims with discharge dates through September 30, 2017, that are available under the current limited data set (LDS) structure. In order to provide even more information in response to the commenters' request, similar to FY 2016, FY 2017, and FY 2018, for FY 2019, we are making available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the links on the left titled ''FY 2019 IPPS Proposed Rule Home Page'' and then click the link ''FY 2019 Proposed Rule Data Files'') more detailed summary tables by provider with the monthly charges that were used to compute the charge inflation factor. We continue to work with our systems teams and privacy office to explore expanding the information available in the current LDS, perhaps through the provision of a supplemental data file for future rulemaking.

Quarter	Covered charges (January 1, 2016, through December 31, 2016)	Cases (January 1, 2016, through December 31, 2016)	Covered charges (January 1, 2017, through December 31, 2017)	Cases (January 1, 2017, through December 31, 2017)
1	$140,753,065,878	2,506,525	$149,358,509,178	2,551,065
2	135,409,469,345	2,414,710	140,445,911,726	2,397,110
3	132,239,610,957	2,356,131	135,004,161,478	2,293,958
4	138,440,787,173	2,412,708	108,175,925,297	1,821,225
Total	546,842,933,353	9,690,074	532,984,507,679	9,063,358

Under this methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2019, we compared the average covered charge per case of $56,433 ($546,842,933,353/9,690,074) from the second quarter of FY 2016 through the first quarter of FY 2017 (January 1, 2016, through December 31, 2016) to the average covered charge per case of $58,806.52 ($532,984,507,679/9,063,358) from the second quarter of FY 2017 through the first quarter of FY 2018 (January 1, 2017, through December 31, 2017). This rate-of-change was 4.2 percent (1.04205) or 9.5 percent (1.085868) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

As we have done in the past, in this proposed rule, we are proposing to establish the proposed FY 2019 outlier threshold using hospital CCRs from the December 2017 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 below to hospitals assigned the statewide average CCR.

For FY 2019, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We are proposing that, if more recent data became available, we would use that data to calculate the final FY 2019 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 2017 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2016 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2017 update of the PSF. We note that we used total transfer-adjusted cases from FY 2017 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 one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, for the proposed rule, we calculated a proposed December 2016 operating national average case-weighted CCR of 0.266065 and a proposed December 2017 operating national average case-weighted CCR of 0.262830. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2016 operating national average case-weighted CCR from the December 2017 operating national average case-weighted CCR and then dividing the result by the December 2016 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.987842.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a December 2016 capital national average case-weighted CCR of 0.023104 and a December 2017 capital national average case-weighted CCR of 0.022076. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2016 capital national average case-weighted CCR from the December 2017 capital national average case-weighted CCR and then dividing the result by the December 2016 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.955517.

As discussed in section III.B.3. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.G.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments were applied after rural floor budget neutrality adjustments were applied for all labor market areas, in order to ensure that no hospital in a frontier State would receive a wage index less than 1.0000 due to the proposed rural floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2019, it was necessary to adjust the proposed wage index of those eligible hospitals in a frontier State when calculating the proposed outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2019. If we did not take the above into account, our estimate of total FY 2019 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.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2019 outlier payments, we are proposing not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that 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 period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

As described in sections IV.H. and IV.I., 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 estimated 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 2019, 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 2019, we are proposing to include estimated FY 2019 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. We used a threshold of $27,545 and calculated total operating Federal payments of $92,908,351,672 and total outlier payments of $4,738,377,622. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we are proposing an outlier fixed-loss cost threshold for FY 2019 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 $27,545.

(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 lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2019 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.06 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2019 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2019 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.949367

We are proposing to apply the outlier adjustment factors to the proposed FY 2019 payment rates after removing the effects of the FY 2018 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 1.167 or capital CCRs greater than 0.154, 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 above range. These statewide average ratios would be effective for discharges occurring on or after October 1, 2018 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 2019 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. 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 we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered 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 Change Request 3966. 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 Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS website: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) Alternative Considered for a Potential Change to the CCRs Used for Outliers, New Technology Add-On Payments, and Payments to IPPS-Excluded Cancer Hospitals for Chimeric Antigen Receptor (CAR) T-Cell Therapy

As discussed in section II.F.2.d. of the preamble of this proposed rule, we have received many inquiries from the public regarding payment of CAR T-cell therapy. For FY 2019, one suggestion from the public was to allow hospitals to utilize a CCR specific to the ICD–10–PCS procedure codes used to report the performance of procedures involving the use of CAR T-cell therapy drugs, for example a CCR of 1.0, when determining whether an individual case qualifies for FY 2019 outlier payments and to determine the cost of an individual case for FY 2019 for purposes of a new technology add-on payment, if approved. As previously discussed, procedures involving the use of CAR T-cell therapy drugs are currently 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 both became effective October 1, 2017.

Two CAR T-cell therapy drugs received FDA approval in 2017. KYMRIAH™ (manufactured by Novartis Pharmaceuticals Corporation) was approved for the use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. YESCARTA™ (manufactured by Kite Pharma, Inc.) was approved for the use in the treatment of adult patients with certain types of large B-cell lymphoma and who have not responded to or who have relapsed after at least two other kinds of treatment.

As discussed in greater detail in section II.H.5.a. of the preamble of this proposed rule, the manufacturer of KYMRIAH™ and the manufacturer of YESCARTA™ submitted separate applications for new technology add-on payments for FY 2019. We believe that, in the context of these pending new technology add-on payment applications, there may also be merit in the suggestion from the public to allow hospitals to utilize a CCR specific to procedures involving the ICD–10–PCS procedures codes describing CAR T-cell therapy drugs for FY 2019 as part of the determination of the cost of a case for purposes of calculating outlier payments for individual FY 2019 cases, new technology add-on payments, if approved, for individual FY 2019 cases, and payments to IPPS-excluded cancer hospitals beginning in FY 2019. For example, a CCR of 1.0 could be used for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3, as many public inquirers believed hospitals would be unlikely to set charges different from costs for the use of KYMRIAH™ and YESCARTA™. Such a change would result in a higher outlier payment, higher new technology add-on payment, or the determination of higher costs for IPPS-excluded cancer hospital cases. For example, if a hospital charged $400,000 for the procedure described by ICD–10–PCS procedure code XW033C3, the application of a hypothetical CCR of 0.25 results in a cost of $100,000 (= $400,000 * 0.25) while the application of a hypothetical CCR of 1.00 results in a cost of $400,000 (= $400,000 * 1.0).

We are inviting public comments on this alternative approach for FY 2019.

We also are inviting comments on how this payment alternative would affect access to care, as well as how it affects incentives to encourage lower drug prices, which is a high priority for this Administration. In addition, we are considering alternative approaches and authorities to encourage value-based care and lower drug prices. We solicit comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches.

(4) FY 2017 Outlier Payments

Our current estimate, using available FY 2017 claims data, is that actual outlier payments for FY 2017 were approximately 5.53 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2017, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2017. 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 2017 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 2018 will not be available until after September 30, 2018, we are unable to provide an estimate of actual outlier payments for FY 2018 based on FY 2018 claims data in this proposed rule. We will provide an estimate of actual FY 2018 outlier payments in the FY 2020 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2019 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 2019. 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 2019.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2019 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similar to above, 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 2018 national standardized amount to the proposed FY 2019 national standardized amount. The second through fifth columns display the changes from the FY 2018 standardized amounts for each applicable proposed FY 2019 standardized amount. The first row of the table shows the updated (through FY 2018) average standardized amount after restoring the FY 2018 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 2018 adjustment factors are not removed from this table.

CHANGES FROM FY 2018 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2019 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 2018 Base Rate after removing: 1. FY 2018 Geographic Reclassification Budget Neutrality (0.987985). 2. FY 2018 Operating Outlier Offset (0.948998).	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36 Nonlabor (30.4%): $1,884.07 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92 Nonlabor (38%): $2,258.50	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36 Nonlabor (30.4%): $1,884.07 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92 Nonlabor (38%): $2,258.50	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36 Nonlabor (30.4%): $1,884.07 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92 Nonlabor (38%): $2,258.50	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,059.36 Nonlabor (30.4%): $1,884.07 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,684.92 Nonlabor (38%): $2,258.50
Proposed FY 2019 Update Factor	1.0125	0.9915	1.0055	0.9845
Proposed FY 2019 MS–DRG Recalibration Budget Neutrality Factor.	0.997896	0.997896	0.997896	0.997896
Proposed FY 2019 Wage Index Budget Neutrality Factor.	1.001182	1.001182	1.001182	1.001182
Proposed FY 2019 Reclassification Budget Neutrality Factor.	0.987084	0.987084	0.987084	0.987084
Proposed FY 2019 Operating Outlier Factor	0.948999	0.948999	0.948999	0.948999
Proposed FY 2019 Rural Demonstration Budget Neutrality Factor.	0.999325	0.999325	0.999325	0.999325
Adjustment for FY 2019 Required under Section 414 of Public Law 114–10 (MACRA).	1.005	1.005	1.005	1.005
Proposed National Standardized Amount for FY 2019 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7).	Labor: $3,863.17 Nonlabor: $1,793.01	Labor: $3,783.04 Nonlabor: $1,755.82	Labor: $3,836.46 Nonlabor: $1,780.61	Labor: $3,756.34 Nonlabor: $1,743.43
Proposed National Standardized Amount for FY 2019 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/0;38).	Labor: $3,506.83 Nonlabor: $2,149.35	Labor: $3,434.09 Nonlabor: $2,104.77	Labor: $3,482.58 Nonlabor: $2,134.49	Labor: $3,409.86 Nonlabor: $2,089.91

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 2019. 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 2019, 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 2019 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 above. 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 2019 that were used in FY 2018 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the proposed COLA factors for FY 2019.

PROPOSED FY2019 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

General Formula for Calculation of the Prospective Payment Rates for FY 2019

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 2019 equals the Federal rate (which includes uncompensated care payments).

Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 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 2019 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2019 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 below. 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.

1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below 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 above) 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 for each claim based on

the ICD–10–CM procedure and diagnosis 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 above.

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 formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

2. 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 above, as discussed in section IV.G. of the preamble of this FY 2019 IPPS/LTCH PPS proposed rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Section 50205 of the Bipartisan Budget Act of 2018, enacted February 9, 2018, extended the MDH program for discharges on or after October 1, 2017 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 2019

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 2019	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	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.25	−0.85	0.55	−1.55

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 proposed hospital-specific rate for an SCH or an MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.997896, as discussed in section III. 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, 2018. We note that, in this proposed rule, for FY 2019, we are not making 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 2019

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. Below we discuss the factors that we used to determine the proposed capital Federal rate for FY 2019, which would be effective for discharges occurring on or after October 1, 2018.

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 Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2019

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2019. In particular, we explain why the proposed FY 2019 capital Federal rate would increase approximately 1.28 percent, compared to the FY 2018 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge will increase approximately 1.7 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

a. Description of the Update Framework

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 2019 under that framework is 1.2 percent based on a projected 1.2 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 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 2019 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2019.

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''); and
- 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 2019, 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 2019. 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 2019 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 2017 DRG reclassification and recalibration as part of our proposed update for FY 2019. We assume, for purposes of this adjustment, that the estimate of FY 2017 DRG reclassification and recalibration resulted 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 2019.

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 2017 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2017 CIPI (1.2 percent) used in calculating the FY 2017 update factor was 0.0 percentage point higher than actual realized price increases (1.2 percent). As this does not exceed the 0.25 percentage point threshold, we are not proposing to make an adjustment for forecast error in the update for FY 2019.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated 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 reflected 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. The capital update framework thus 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 2019 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2019, 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 2012 and extending through FY 2016. Based on these data, we estimated that case-mix constant intensity declined during FYs 2012 through 2016. 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 estimate that intensity will decline during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2019. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2019.

Above, we described the basis of the components we used to develop the proposed 1.2 percent capital update factor under the capital update framework for FY 2019 as shown in the following table.

PROPOSED CMS FY 2019 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.2
Intensity	0.0
Case-Mix Adjustment Factors	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2017 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Proposed Total Update	1.2

*The capital input price index represents the 2014-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2018 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2019. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2018, Chapter 3, available on the website at: *http://www.medpac.gov*.)

2. Proposed Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds 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 thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2018, we estimated that outlier payments for capital would equal 5.17 percent of inpatient capital-related payments based on the capital Federal rate in FY 2018. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs would equal 5.06 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2019. Therefore, we are proposing to apply an outlier adjustment factor of 0.9494 in determining the capital Federal rate for FY 2019. Thus, we estimate that the percentage of capital outlier payments to proposed total capital Federal rate payments for FY 2019 would be lower than the percentage for FY 2018.

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 2019 outlier adjustment of 0.9494 is a 0.12 percent change from the FY 2018 outlier adjustment of 0.9483. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2019 is 1.0012(0.9494/0.9483) so that the proposed outlier adjustment would increase the FY 2019 capital Federal rate by 0.12 percent compared to the FY 2018 outlier adjustment.

3. Proposed 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. The budget neutrality factor for DRG reclassifications and recalibration nationally is applied in determining the capital IPPS Federal rate, and is applicable for all hospitals, including those hospitals located in Puerto Rico.

To determine the proposed factors for FY 2019, we compared estimated aggregate capital Federal rate payments based on the FY 2018 MS–DRG classifications and relative weights and the FY 2018 GAF to estimated aggregate capital Federal rate payments based on the FY 2018 MS–DRG classifications and relative weights and the proposed FY 2019 GAFs. To achieve budget neutrality for the changes in the GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment factor of 1.000094 for FY 2019 to the previous cumulative FY 2018 adjustment factor.

We then compared estimated aggregate capital Federal rate payments based on the FY 2018 MS–DRG relative weights and the proposed FY 2019 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2019 MS–DRG classifications and relative weights and the proposed FY 2019 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9996. The proposed incremental adjustment factors for MS–DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2019 is 0.9997. 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 MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental adjustment factor of 0.9997 (the product of the proposed incremental national GAF budget neutrality

adjustment factor of 1.00009 and the proposed incremental DRG budget neutrality adjustment factor of 0.9996) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2019 geographic reclassification decisions made by the MGCRB compared to FY 2018 decisions. 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 2019

For FY 2018, we established a capital Federal rate of $453.95 (82 FR 46144 through 46145). We are proposing to establish an update of 1.2 percent in determining the FY 2019 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 $459.78 for FY 2019. The proposed national capital Federal rate for FY 2019 was calculated as follows:

- The proposed FY 2019 update factor is 1.012; that is, the proposed update is 1.2 percent.
- The proposed FY 2019 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9997.
- The proposed FY 2019 outlier adjustment factor is 0.9494.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2019 affects the computation of the proposed FY 2019 national capital Federal rate in comparison to the FY 2018 national capital Federal rate as presented in the FY 2018 IPPS/LTCH PPS Correction Notice (82 FR 46144 through 46145). The proposed FY 2019 update factor has the effect of increasing the capital Federal rate by 1.2 percent compared to the FY 2018 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.03 percent. The proposed FY 2019 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.12 percent compared to the FY 2018 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 1.28 percent compared to the FY 2018 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2018 CAPITAL FEDERAL RATE AND PROPOSED FY 2019 CAPITAL FEDERAL RATE

	FY 2018	Proposed FY 2019	Proposed change	Proposed percent change
Update Factor [1]	1.0130	1.012	1.012	1.20
GAF/DRG Adjustment Factor [1]	0.9987	0.9997	.09997	−0.03
Outlier Adjustment Factor [2]	0.9483	0.9494	1.0012	0.12
Capital Federal Rate	$453.95	$459.78	1.0128	[3] 1.28

[1] The 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 2018 to FY 2019 resulting from the application of the proposed 0.9997 GAF/DRG budget neutrality adjustment factor for FY 2019 is a net change of 0.9997 (or –0.03 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 2019 outlier adjustment factor is 0.9494/0.9483 or 1.0012 (or 0.12 percent).

[3] Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2019

For purposes of calculating payments for each discharge during FY 2019, 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 thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2019 are in section II.A. of this Addendum. For FY 2019, a case would 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.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $27,545.

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 2019 IPPS/LTCH PPS proposed rule, we are using 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.

2. Forecast of the CIPI for FY 2019

Based on IGI's fourth quarter 2017 forecast, for this proposed rule, we are forecasting the 2014-based CIPI to increase 1.2 percent in FY 2019. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.0 percent increase in other capital expense prices in FY 2019, partially offset by a projected 1.3 percent decline in vintage-weighted interest expense prices in FY 2019. The weighted average of these three factors produces the forecasted 1.2 percent increase for the 2014-based CIPI in FY 2019.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2019

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.)

The proposed FY 2019 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, RNHCIs, and extended neoplastic disease care hospitals is the estimated percentage increase in the IPPS operating market basket for FY 2019, in accordance with applicable regulations at § 413.40. Based on IGI's 2017 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2019 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). However, we are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2019. Therefore, for children's hospitals, the 11 cancer hospitals, 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), extended neoplastic disease care hospitals, and RNHCIs, the FY 2019 rate-of-increase percentage that would be applied to the FY 2018 target amounts, in order to determine the proposed FY 2019 target amounts is 2.8 percent.

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 proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2019. 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 2019

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2019

1. Overview

In section VII. of the preamble of this proposed rule, we discuss our proposed annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2019.

Under § 412.523(c)(3) of the regulations, for LTCH PPS FYs 2012 through 2017, 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)(A)(i) (citing sections 1886(b)(3)(B)(xi)(II), 1886(m)(3)(A)(ii), and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (c)(3)(xiii)). (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).) Sections 1886(m)(3)(A) and 1886(m)(3)(C) of the Act specify that, for rate year 2010 and each subsequent rate year, except FY 2018, any annual update to the standard Federal payment rate shall be reduced:

- For rate year 2010 through 2019, by the ''other adjustment'' specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, 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.D.2. of the preamble of this proposed rule.

This section of the Act further provides that the application of section 1886(m)(3) 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.D.2.a. 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 2019 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2019, 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 2019, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2019 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4) and a proposed budget neutrality adjustment factor for the proposed elimination of the 25-percent threshold policy (discussed in VII.D. of the preamble of this proposed rule).

In this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.15 percent. Accordingly, under proposed § 412.523(c)(3)(xv), we are proposing to apply a factor of 1.0115 to the FY 2018 LTCH PPS standard Federal payment rate of $41,415.11 to determine the proposed FY 2019 LTCH PPS standard Federal payment rate. Also, under proposed § 412.523(c)(3)(xv), applied in conjunction with the provisions of § 412.523(c)(4), we are proposing an annual update to the LTCH PPS standard Federal payment rate of -0.85 percent (that is, a proposed update factor of 0.9915) for FY 2019 for LTCHs that fail to submit the required quality reporting data for FY 2019 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are proposing to apply an area wage level budget neutrality factor to the proposed FY 2019 LTCH PPS standard Federal payment rate of 0.999713 based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal rate payments. Finally, we are proposing to apply a one-time, permanent budget neutrality adjustment of 0.990535 for our proposed elimination of the 25-percent threshold policy (discussed in VII.E. of the preamble of this proposed rule). Accordingly, we are proposing an LTCH PPS standard Federal payment rate of $41,482.98 (calculated as $41,415.11 × 1.0115 × 0.999713 × 0.990535) for FY 2019 (calculations performed on rounded numbers). For LTCHs that fail to submit quality reporting data for FY 2019, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing an LTCH PPS standard Federal payment rate of $40,662.75 (calculated as $41,415.11 × 0.9915 × 0.999713 × 0.990535) (calculations performed on rounded numbers) for FY 2019.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2019

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.

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. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf.*)

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. 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. We adopted these labor market area delineations because they are 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 believe that these OMB delineations will 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. 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. 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. We adopted the updates contained in OMB Bulletin No. 15–01, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913 through 56914). On August 15, 2017, OMB issued OMB Bulletin No. 17–01 that updated and superseded Bulletin No. 15–01. As discussed in section III.A.2. of the preamble of this proposed rule, OMB Bulletin No. 17–01 and its attachments provide detailed information on the update to statistical areas since the July 15, 2015 release of Bulletin No. 15–01 and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014, and July 1, 2015. 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.*

OMB Bulletin No. 17–01 made the following change that is relevant to the LTCH PPS CBSA-based labor market area (geographic classification) delineations:

- Twin Falls, ID, with principal city Twin Falls, ID and consisting of counties Jerome County, ID and Twin Falls County, ID, which was a Micropolitan (geographically rural) area, now qualifies as an urban area under new CBSA 46300 entitled Twin Falls, ID.

This change affects all providers located in CBSA 46300, but our database shows no LTCHs located in CBSA 46300.

We believe that this revision to the CBSA-based labor market area delineations will 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 this revision under the LTCH PPS, effective October 1, 2018. Accordingly, the proposed FY 2019 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 revision to the CBSA-based labor market area delineations described above. We note that, as discussed in section III.A.2. of the preamble of this proposed rule, the revision to the CBSA-based delineations also is being proposed under the IPPS.

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 PPS 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-specific 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-specific 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).) As noted previously, we rebased and revised the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that policy, as discussed in section VII.D. of the preamble of this FY 2019 IPPS/LTCH PPS proposed rule, we are proposing to establish that the LTCH PPS labor-related share for FY 2019 is the sum of the FY 2019 relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data.

Specifically, we are proposing to establish that the labor-related share for FY 2019 includes the sum of the labor-related portion of operating costs from the 2013-based LTCH market basket (that is, the sum of the FY 2019 relative importance share 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 2013-based LTCH PPS market basket. Based on IGI's fourth quarter 2017 forecast of the 2013-based LTCH market basket, we are proposing to establish a labor-related share under the LTCH PPS for FY 2019 of 66.2 percent. This labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, we also are proposing that if more recent data become available, we would use that data, if appropriate, to determine the final FY 2019 labor-related share in the final rule. (We note that a labor-related share of 66.2 percent is the same as the labor-related share for FY 2018. Although the relative importance of some components of the market basket have changed, the proposed labor-related share remains at 66.2 percent when aggregating these components and rounding to one decimal.)

The proposed labor-related share for FY 2019 is the sum of the FY 2019 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (2013) and FY 2019. The sum of the relative importance for FY 2019 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) is 62.0 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our policies is 9.1 percent of the 2013-based LTCH market basket in FY 2019, we are proposing to take 46 percent of 9.1 percent to determine the labor-related share of capital-related costs for FY 2019 (0.46 x 9.1). The result is 4.2 percent, which we added to 62.0 percent for the operating cost amount to determine the total proposed labor-related share for FY 2019. Therefore, we are proposing that the labor-related share under the LTCH PPS for FY 2019 is 66.2 percent.

4. Proposed Wage Index for FY 2019 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 2018 IPPS/LTCH PPS final rule (82 FR 38538 through 38539), we calculated the FY 2018 LTCH PPS area wage index values using the same data used for the FY 2018 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2014), 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 2018 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, as discussed in this FY 2019 IPPS/LTCH PPS proposed rule, to determine the applicable area wage index values for the FY 2019 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 use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2015, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act because these data are the most recent complete data available. We also note that these are the same data we are using to compute the FY 2019 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. We are proposing to compute the proposed FY 2019 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, labor market area delineations, including the proposed 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 also are proposing to continue to apportion 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 2019, 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 2015 IPPS wage data that we are proposing to use to determine the proposed FY 2019 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2019 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). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2015 IPPS wage data that we are proposing to use to determine the proposed FY 2019 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 proposed rural areas with no IPPS wage data for FY 2019. 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. The proposed FY 2019 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, 2018, through September 30, 2019, 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.

5. Proposed Budget Neutrality Adjustment 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 will be 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 apply 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).) In this proposed rule, for FY 2019 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). 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 2019 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2018 wage index values and the FY 2018 labor-related share of 66.2 percent (as established in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38314 and 38315)).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2019 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the internet on the CMS website) and the proposed FY 2019 labor-related share of 66.2 percent (based on the latest available data as previously discussed in this Addendum).

Step 3—We calculated 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 2018 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2019 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2019 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the proposed FY 2019 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2019 LTCH PPS standard Federal payment rate after the application of the proposed FY 2019 annual update (discussed previously in section V.A. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate

provisions and certain temporary exemptions for certain spinal cord specialty hospitals and certain severe wound cases, 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 (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate had been in effect at the time of discharge to calculate the FY 2019 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2019 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.999713. Accordingly, in section V.A. of the Addendum to this proposed rule, to determine the proposed FY 2019 LTCH PPS standard Federal payment rate, we are proposing to apply an area wage level adjustment budget neutrality factor of 0.999713, in accordance with § 412.523(d)(4). The proposed FY 2019 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

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 described above 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 2019, 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).) Consistent with our historical practice, we are proposing to establish that the COLA factors shown in the following table will be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2019

Area	FY 2018 and proposed FY 2019
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

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 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 2-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 above, 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. LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the most recent data to determine the LTCH total CCR ceiling for FY 2019 in this proposed rule. Specifically, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2017 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 1.28 under the LTCH PPS for FY 2019 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. (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. 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, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2017 update of the PSF, 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, 2018, through September 30, 2019, 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 also are proposing that if more recent data become available, we would use that data to determine the LTCH PPS statewide average total CCRs for FY 2019 in the final rule.

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 has 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 that area as of December 2017. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one provider whose CCR is an atypical 1.215. Because this is much higher than the statewide urban average and furthermore implies costs exceeded charges, as with Connecticut, we are proposing to use the national average total CCR for rural hospitals for hospitals located in rural Massachusetts. Furthermore, consistent with our existing methodology, in determining the 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 using 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. 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. Establishment of the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2019

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 FY 2019 IPPS/LTCH PPS 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 2019 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 proposed payment rates and policies for these cases presented in this proposed rule). Specifically, based on the most recent complete LTCH data available at this time (that is, LTCH claims data from the December 2017 update of the FY 2017 MedPAR file and CCRs from the December 2017 update of the PSF), we are proposing to determine a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 of $30,639 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2019 payments for such cases. Under this proposal, we would 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 $30,639).

We note that the proposed fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate in FY 2019 of $30,639 is higher than the FY 2018 fixed-loss amount of $27,381 for LTCH PPS standard Federal payment rate cases. However, based on the most recent available data at the time of the development of this FY 2019 IPPS/LTCH PPS proposed rule, we found that the current FY 2018 HCO threshold of $27,381 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 7.988 percent of the estimated total LTCH PPS payments in FY 2018, which exceeds the 7.975 percent target by 0.01 percentage points. We continue to believe, as discussed in detail in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38543), this increase is largely attributable to the rate-of-change (that is, increase) in the Medicare allowable charges on the claims data in addition to updates to CCRs from the December 2016 update of the PSF to the March 2017 update of the PSF. Consistent with our historical practice of using the best data available, we are proposing that, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2019 in the final rule, we would use the most recent available LTCH claims data and CCR data at the time.

3. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80 FR 49618 through 49629). In the following discussion, we note that 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 2016 through 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 payment rate amount for the discharge (§ 412.522(c)(3)). As such, for FY 2019 discharges paid under the transitional payment method, the discussion below pertains only to the site neutral payment rate portion of the blended payment rate under § 412.522(c)(3)(i).

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, we continue to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2017 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2018, 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 2018 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 2018. In particular, in FY 2018, we established the fixed-loss amount for site neutral payment rate cases as the FY 2018 IPPS fixed-loss amount of $26,537 (82 FR 46145).

As noted earlier, because not all claims in the data used for this proposed rule were subject to the site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2018 when developing a proposed fixed-loss amount for site neutral payment rate cases for FY 2019. Because our actuaries continue to project that site neutral payment rate cases in FY 2019 will continue to mirror an IPPS case paid under the same MS–DRG, we continue to believe that it would be inappropriate 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. More specifically, as with FYs 2016 through 2018, our actuaries project that the costs and resource use for FY 2019 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 is found based on the

historical data. (Based on the most recent FY 2017 LTCH claims data, approximately 64 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 36 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2017.)

For these reasons, we continue to believe that the most appropriate proposed fixed-loss amount for site neutral payment rate cases for FY 2019 is the proposed IPPS fixed-loss amount for FY 2019. Therefore, consistent with past practice, in this FY 2019 IPPS/LTCH PPS proposed rule, for FY 2019, 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 proposed IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $27,545, which is the same proposed FY 2019 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to this proposed rule. We continue to believe that this policy would reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, for FY 2019, we are proposing 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 proposed site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $27,545).

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 2019 would not result in any increase in estimated aggregate FY 2019 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments (or the portion of the blended payment rate payment for FY 2018 discharges occurring in LTCH cost reporting periods beginning before October 1, 2017) by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2019. In order to achieve this, for FY 2019, in general, we are proposing to continue to use the policy adopted for FY 2018.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate our proposed fixed-loss threshold of $27,545 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 2019 would not result in any increase in estimated aggregate FY 2019 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 2019. In order to achieve this, for FY 2019, 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 the policy adopted for FY 2018, 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/Equivalent Amounts 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 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. 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, 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 is 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 2019, as discussed in greater detail in section IV.F.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 67.51 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 amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2018. 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 will be adjusted to 50.63 percent (the product of 75 percent and 67.51 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2019, 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 75.63 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 + 50.63 percent = 75.63 percent).

In this FY 2019 IPPS/LTCH PPS proposed rule, for FY 2019, 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 75.63 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, if appropriate, we will use that data to determine this factor in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2019

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 proposed labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2019 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 2019 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 2019 of $41,482.98, 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 2019 in the following example:

Example:

During FY 2019, 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 Chicago, Illinois (CBSA 16974). The proposed FY 2019 LTCH PPS wage index value for CBSA 16974 is 1.0511 (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 2019 of 0.9595 (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 2019 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2019, we computed the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted proposed FY 2019 LTCH PPS standard Federal payment rate ($41,482.98) by the proposed labor-related share (66.2 percent) and the wage index value (1.0511). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (33.8 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9595) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2019 ($41,149.38). The table below illustrates the components of the calculations in this example.

Proposed Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$41,482.98
Proposed Labor-Related Share	× 0.662
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $27,461.73
Proposed Wage Index (CBSA 16974)	× 1.0511
Proposed Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $28,865.02
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($41,482.98 x 0.338)	+ $14,021.25
Proposed Adjusted LTCH PPS Standard Federal Payment Amount	= $42,886.27
Proposed MS–LTC–DRG 189 Relative Weight	× 0.9595
Proposed Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $41,149.38

VI. Tables Referenced in This Proposed Rule Generally Available Only Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in this 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 2018, for the FY 2019 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 only through the internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will generally only 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.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49807), we streamlined and consolidated the wage index tables for FY 2016 and subsequent fiscal years.

As discussed in section III.J. of the preamble to this proposed rule, we are adding a new Table 4, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019,'' associated with this proposed rule. This table consists of the following: A list of counties that would be eligible for the out-migration adjustment for FY 2019 identified by FIPS county code, the proposed FY 2019 out-migration adjustment, and the number of years the adjustment would be in effect. We believe this new table would make this information more transparent and provide the public with easier access to this information. We intend to make the information available annually via Table 4 in the IPPS/LTCH PPS proposed and final rules, and are including it among the tables associated with this FY 2019 IPPS/LTCH PPS proposed rule that are available via the internet on the CMS website.

As discussed in sections II.F.13., II.F.15.b. and d., II.F.16., and II.F.18. of the preamble of this proposed rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2019: Table 6A.—New Diagnosis Codes; Table 6B.—New Procedure Codes; Table 6C.—Invalid Diagnosis Codes; Table 6D.—Invalid Procedure Codes; Table 6E.—Revised Diagnosis Code Titles; Table 6F.—Revised Procedure Code Titles; Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusion List; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I.1.—Proposed Additions to the MCC List; Table 6I.2.—Proposed Deletions to the MCC List; Table 6J.1.—Proposed Additions to the CC List; Table 6J.2.—Proposed Deletions to the CC List; and Table 6P.— ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes. Table 6P contains multiple tables, 6P.1 through 6P.1k, that include the ICD–10–CM and ICD–10–PCS code lists relating to specific proposed MS–DRG changes. 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. However, as discussed in section IV.K. of the preamble of this proposed rule, we are not providing the hospital-level data as a table associated with this proposed rule. The hospital-level data for the FY 2019 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As discussed in section II.H.1. of the preamble of this proposed rule, Table 10 that we have released in prior fiscal years contained the thresholds that we use to evaluate applications for new medical service and technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. In an effort to clarify for the public that the listed thresholds will be used for new technology add-on payment applications for the next fiscal year (in this case, for FY 2020) rather than the fiscal year that is otherwise the subject of the rulemaking (in this case, for FY 2019), we are proposing to provide the thresholds previously included in Table 10 as one of our publicly available data files

posted via the internet on the CMS website for the rulemaking for the upcoming fiscal year at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html,* which is the same URL where the impact data files associated with the rulemaking for the applicable fiscal year are posted. We refer readers to section II.H.1. of the preamble of this proposed rule regarding our proposal to include the thresholds previously included in Table 10 as one of our public data files.

As discussed in section VII.B of the preamble of this proposed rule, in previous fiscal years, Table 13A.—Composition of Low-Volume Quintiles for MS–LTC–DRGs (which was listed in section VI. of the Addendum to the proposed and final rules and available via the internet on the CMS website) listed the composition of the low-volume quintiles for MS–LTC–DRGs for the respective year, and Table 13B.—No Volume MS–LTC–DRG Crosswalk (also listed in section VI. of the Addendum to the proposed and final rules and available via the internet on the CMS website) listed the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs). The information contained in Tables 13A and 13B is used in the development of Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges, which contains 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) for the respective fiscal year (and also is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). Because the information contained in Tables 13A and 13B does not contain proposed payment rates or factors for the applicable payment year, we are proposing to generally provide the data previously published in Tables 13A and 13B for each annual proposed rule and final rule as one of our supplemental data files via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* (that is, the same URL address where the impact data files associated with the rule are posted). To streamline the information made available to the public that is used in the annual development of Table 11, we believe that this proposed change in the presentation of the information contained in Tables 13A and 13B will make it easier for the public to navigate and find the relevant data and information used for the development of proposed payment rates or factors for the applicable payment year, while continuing to furnish the same information contained in the tables provided in previous fiscal years.

In addition, Table 18 associated with this proposed rule contains the proposed Factor 3 for purposes of determining the FY 2019 uncompensated care payment for all hospitals and identifies whether or not a hospital is projected to receive Medicare DSH payments and, therefore, eligible to receive the additional payment for uncompensated care for FY 2019. A hospital's Factor 3 determines the proportion of the aggregate amount available for uncompensated care payments that a Medicare DSH eligible hospital will receive under section 3133 of the Affordable Care Act.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this FY 2019 proposed rule are generally only 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 2019 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download.''

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2019
Table 3.—Proposed Wage Index Table by CBSA—FY 2019
Table 4.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019
Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2019
Table 6A.—New Diagnosis Codes—FY 2019
Table 6B.—New Procedure Codes—FY 2019
Table 6C.—Invalid Diagnosis Codes—FY 2019
Table 6D.—Invalid Procedure Codes—FY 2019
Table 6E.—Revised Diagnosis Code Titles—FY 2019
Table 6F.—Revised Procedure Code Titles—FY 2019
Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2019
Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2019
Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2019
Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2019
Table 6I.1.—Proposed Additions to the MCC List—FY 2019
Table 6I.2.—Proposed Deletions to the MCC List—FY 2019
Table 6J.1.—Proposed Additions to the CC List—FY 2019
Table 6J.2.—Proposed Deletions to the CC List—FY 2019
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes—FY 2019
Table 7A.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2017 MedPAR Update—September 2017 GROUPER V35.0 MS–DRGs
Table 7B.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2017 MedPAR Update— September 2017 GROUPER V36.0 MS–DRGs
Table 8A.—Proposed FY 2019 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—Proposed FY 2019 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 15.—Proposed Proxy FY 2019 Readmissions Adjustment Factors
Table 16.—Proposed Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2019
Table 18.—Proposed FY 2019 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2019 proposed rule are available only 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–1694–P:

Table 8C.—Proposed FY 2019 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, 2018 through September 30, 2019
Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2018 through September 30, 2019
Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2018 through September 30, 2019

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 2019]

Hospital submitted quality data and is a meaningful EHR user (Update = 1.25 Percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.85 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.550 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.55 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,863.17	$1,793.01	$3,783.04	$1,755.82	$3,836.46	$1,780.61	$3,756.34	$1,743.43

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 2019]

Hospital submitted quality data and is a meaningful EHR User (update = 1.25 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.85 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.550 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.55 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,506.83	$2,149.35	$3,434.09	$2,104.77	$3,482.58	$2,134.49	$3,409.86	$2,089.91

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 2019]

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$3,506.83	$2,149.35

[1] For FY 2019, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE

[FY 2019]

	Rate
National	$459.78

TABLE 1E—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE

[FY 2019]

	Full update (1.15 percent)	Reduced update * (−0.85 percent)
Standard Federal Rate	$41,482.98	$40,662.75

* For LTCHs that fail to submit quality reporting data for FY 2019 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.

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.

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 2019 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The 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 $4.1 billion increase in FY 2019 payments, primarily driven by a combined $4.0 billion increase in FY 2019 operating payments and uncompensated care payments, and a combined $0.1 billion increase in FY 2019 capital payments and low-volume hospital payments. These proposed changes are relative to payments made in FY 2018. The impact analysis of the proposed 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 $5 million in FY 2019 relative to FY 2018.

Our operating impact estimate includes the proposed 0.5 percent 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 1.25 percent hospital update to the standardized amount (which includes the estimated 2.8 percent market basket update less 0.8 percentage point for the proposed multifactor productivity adjustment and less 0.75 percentage point required under the Affordable Care Act). The estimates of proposed IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which would 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 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 will 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 rational 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 2019, 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, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix. 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 29 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 All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 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 2018, there were 3,257 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 1,395 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, extended neoplastic disease care hospitals, and 5 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 2019 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2018, there were 98 children's hospitals, 11 cancer hospitals, 5 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 18 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, 280 rehabilitation hospitals and 844 rehabilitation units, and approximately 409 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 538 psychiatric hospitals and 1,098 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the 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 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, and RNHCIs, the update of the rate-of-increase limit (or target amount) would be the estimated FY 2019 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 2017 fourth quarter forecast of the 2014-based IPPS market basket increase, we are estimating the FY 2019 update to be 2.8 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 them to calculate the IPPS operating market basket update for FY 2019. However, the Affordable Care Act requires an adjustment for multifactor productivity (currently proposed at 0.8 percentage point for FY 2019) and a 0.75 percentage point reduction to the market basket update, resulting in a proposed 1.25 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 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, extended neoplastic disease care hospitals, 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 2019, estimated at 2.8 percent, without the reductions described previously under the Affordable Care Act.

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 2019 for operating costs of acute care hospitals. The proposed FY 2019 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that proposed total FY 2019 operating payments would increase by 2.1 percent, compared to FY 2018. In addition to the applicable percentage increase, this amount reflects the proposed 0.5 percent permanent adjustment to the standardized amount required under section 414 of the 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 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 2017 MedPAR file and the most current Provider-Specific File (PSF) that is 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 2017 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 2019 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the proposed application of the adjustment required under section 414 of the MACRA and the applicable percentage increase (including the proposed market basket update, the proposed multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and 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 2015, compared to the FY 2014 wage data, to calculate the proposed FY 2019 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that would be effective for FY 2019.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index, and the proposed expiration of the imputed floor.
- 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 proposed 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 2019. This provision is not budget neutral.
- The total estimated change in proposed payments based on the proposed FY 2019 policies relative to payments based on FY 2018 policies that include the proposed applicable percentage increase of 1.25 percent (or proposed 2.8 percent market basket update with a proposed reduction of 0.8 percentage point for the multifactor productivity adjustment, and a 0.75 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2019 changes, our analysis begins with a FY 2018 baseline simulation model using: The FY 2018 applicable percentage increase of 1.35 percent, the 0.4588 percent adjustment to the Federal standardized amount, and the adjustment factor of (1/1.006) to both the national standardized amount and the hospitals specific rate; the FY 2018 MS–DRG GROUPER (Version 35); the FY 2018 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2018 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 Pub. L. 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Public Law 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, for FY 2019, 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 0.55 percent. At the time this impact was prepared, 54 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2019 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 2019 using a reduced update for these hospitals.

For FY 2019, 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, for FY 2019, 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 −0.85 percent. At the time this impact analysis was prepared, 148 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2019 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 2019 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 −1.55 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. At the time this impact was prepared, 43 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2019 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 2019 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our comparison illustrates the proposed percent change in payments per case from FY 2018 to FY 2019. 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 2019 using a proposed applicable percentage increase of 1.25 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.8 percent with a proposed 0.8 percentage point reduction for the multifactor productivity adjustment and a 0.75 percentage point reduction, as required, under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 0.55 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 −0.85 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 an proposed update of −1.55 percent. Under section 1886(b)(3)(B)(iv) of the Act, the proposed update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 1.25 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 2018 to FY 2019 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2018 that would no longer be reclassified in FY 2019. Conversely, payments may increase for hospitals not reclassified in FY 2018 that were reclassified in FY 2019.

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2019. 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 proposed overall impact on the 3,257 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 2,480 hospitals located in urban areas included in our analysis. Among these, there are 1,310 hospitals located in large urban areas (populations over 1 million), and 1,170 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 777 hospitals in rural areas. 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 2019 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other 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 2,281, 1,325, 956, and 976, 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 2,162 nonteaching hospitals in our analysis, 846 teaching hospitals with fewer than 100 residents, and 249 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 328 RRCs, 311 SCHs, 135 MDHs, 133 hospitals that are both SCHs and RRCs, and 14 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 patient days. These data were taken from the FY 2015 or FY 2014 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2019. The second grouping shows the MGCRB rural reclassifications.

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2019

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2019 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2019 Changes (7)[8]
All Hospitals	3,257	1.7	0	0	0	0	0.1	2.1
By Geographic Location:								
Urban hospitals	2,480	1.7	0	0	-0.1	0	0.1	2.1
Large urban areas	1,310	1.7	0.1	0	-0.7	-0.1	0	2.1
Other urban areas	1,170	1.7	0	0	0.5	0.1	0.2	2.1
Rural hospitals	777	1.4	-0.3	-0.1	1.4	-0.2	0.1	1.1
Bed Size (Urban):								
0-99 beds	638	1.6	-0.3	0	-0.7	0	0.2	1.4
100-199 beds	763	1.7	0	0	-0.2	0.1	0.2	1.7
200-299 beds	438	1.7	0	0	0.2	0	0.1	2.1
300-499 beds	427	1.7	0	0	0	-0.1	0.1	2.1
500 or more beds	214	1.7	0.1	0	-0.2	0	0	2.5
Bed Size (Rural):								
0-49 beds	299	1.2	-0.8	0.1	0.5	-0.1	0.3	0.8
50-99 beds	279	1.4	-0.5	-0.1	0.7	-0.1	0.2	1
100-149 beds	116	1.4	-0.3	0.2	1	-0.1	0	1
150-199 beds	44	1.5	-0.2	-0.4	1.9	-0.2	0.2	1

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2019 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2019 Changes (7)[8]
200 or more beds	39	1.6	0	-0.1	2.8	-0.2	-0.1	1.5
Urban by Region:								
New England	113	1.7	0	-0.5	1.3	2.2	0.1	2.8
Middle Atlantic	310	1.7	0.1	0	0.2	-0.3	0.1	1.9
South Atlantic	401	1.7	0	-0.1	-0.4	-0.2	0	1.9
East North Central	385	1.7	0.1	-0.3	-0.3	-0.3	0	1.9
East South Central	147	1.7	0.1	0	-0.2	-0.3	0	2.2
West North Central	158	1.7	0	0	-0.7	-0.2	0.6	2
West South Central	378	1.7	0	0.2	-0.6	-0.2	0	2.1
Mountain	163	1.7	-0.1	-0.6	-0.1	0.1	0.3	1.2
Pacific	374	1.7	0	0.8	0.2	0.3	0.1	3.1
Puerto Rico	51	1.8	-0.3	-1.2	-1.1	0.2	0.1	0.5
Rural by Region:								
New England	20	1.4	0	-0.5	1.7	-0.2	0	0.7
Middle Atlantic	53	1.3	-0.2	0	0.8	-0.1	0	1.2
South Atlantic	122	1.5	-0.3	0.1	2	-0.2	0.1	1.1
East North Central	114	1.4	-0.4	0.1	0.9	-0.1	0	1
East South Central	150	1.6	-0.1	-0.3	2.7	-0.2	0	1.6
West North Central	94	1.2	-0.6	0.1	0.1	-0.1	0.2	0.7
West South Central	147	1.6	-0.5	0.3	1.6	-0.2	0.1	1.2

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2019 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2019 Changes (7)[8]
Mountain	54	1.1	-0.5	-0.8	0.1	-0.1	0.8	0.8
Pacific	23	1.2	-0.4	-0.3	1	-0.1	0	0.9
By Payment Classification:								
Urban hospitals	2,281	1.7	0	0	-0.5	0	0.1	2
Large urban areas	1,325	1.7	0.1	0	-0.6	-0.1	0	2.1
Other urban areas	956	1.7	0	-0.1	-0.2	0.2	0.2	1.9
Rural areas	976	1.6	-0.1	0	1.7	-0.1	0.1	2.1
Teaching Status:								
Nonteaching	2,162	1.7	-0.1	0.1	0.2	0	0.1	1.7
Fewer than 100 residents	846	1.7	0	0	-0.2	0	0.2	1.9
100 or more residents	249	1.7	0.1	0	0	0	0	2.6
Urban DSH:								
Non-DSH	520	1.7	-0.2	-0.1	-0.3	-0.2	0.2	1.6
100 or more beds	1,483	1.7	0.1	0	-0.5	0	0.1	2.1
Less than 100 beds	365	1.7	-0.2	0.2	-0.5	0.1	0.1	1.7
Rural DSH:								
SCH	258	1.2	-0.6	0	0	0	0	0.7
RRC	367	1.6	0	0.1	2.1	0	0.1	2.5
100 or more beds	27	1.7	-0.1	-0.1	1	-0.3	0.1	1.6
Less than 100 beds	127	1.6	-0.1	0.1	0.8	-0.3	0.6	1.9

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2019 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2019 Changes (7)[8]
Urban teaching and DSH:								
Both teaching and DSH	818	1.7	0.1	0	-0.5	0	0.1	2.2
Teaching and no DSH	88	1.8	0	-0.1	-0.6	-0.2	0	1.8
No teaching and DSH	1,030	1.7	0	0.1	-0.2	0.1	0.1	1.9
No teaching and no DSH	345	1.7	-0.2	-0.2	-0.5	-0.2	0.2	1.6
Special Hospital Types:								
RRC	328	1.7	0	0.1	2.3	-0.1	0.2	2.8
SCH	311	1.2	-0.4	0	-0.1	0	0	0.9
MDH	135	1.4	-0.5	0	0.8	-0.1	0.2	0.9
SCH and RRC	133	1.2	-0.2	-0.1	0.5	-0.1	0	1.1
MDH and RRC	14	1.4	-0.5	0.1	0.9	-0.1	0	1.1
Type of Ownership:								
Voluntary	1,901	1.7	0	0	0	0	0.1	2.1
Proprietary	854	1.7	0	-0.1	-0.1	-0.1	0.1	1.7
Government	501	1.6	0	0.2	-0.1	0	0	2.2
Medicare Utilization as a Percent of Inpatient Days:								

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2019 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2019 Changes (7)[8]
0-25	546	1.7	0.1	0	-0.4	-0.1	0	1.9
25-50	2,121	1.7	0	0	0	0	0.1	2.2
50-65	477	1.6	-0.2	0	0.3	0	0.2	1.3
Over 65	73	1.1	0.1	0	-0.3	-0.2	0.1	2
FY 2019 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	911	1.7	0	0.1	2	-0.1	0.1	2.3
Non-Reclassified Hospitals	2,346	1.7	0	-0.1	-1	0.1	0.1	1.9
Urban Hospitals Reclassified	633	1.7	0	0.2	1.9	-0.1	0.1	2.5
Urban Non-reclassified Hospitals	1,795	1.7	0	-0.1	-1	0.1	0.1	2
Rural Hospitals Reclassified Full Year	278	1.5	-0.2	-0.1	2.3	-0.2	0.1	1.3
Rural Non-reclassified Hospitals Full Year	452	1.3	-0.5	-0.1	-0.4	-0.1	0.2	0.7
All Section 401 Reclassified	246	1.7	0	0.1	1.9	0	0.1	2.7

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2019 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2019 Changes (7)[8]
Hospitals:								
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	1.6	-0.3	0	2.5	-0.2	0	1

[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 2017, and hospital cost report data are from reporting periods beginning in FY 2015 and FY 2014.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 1.25 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.8 percent market basket update reduced by 0.8 percentage point for the multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), and the 0.5 percent 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 36 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2017 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 0.997896 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 2015 and 2014 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 1.001182.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2019 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2019. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.987084.

[6] This column displays the effects of the proposed rural floor and proposed expiration of the imputed floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.994733.

[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 proposed change in payments from FY 2018 to FY 2019.

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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 2.8 percent market basket update, the reduction of proposed 0.8 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction, in accordance with the Affordable Care Act. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the FY 2018 +0.5 percent adjustment required under section 414 of the MACRA. As a result, we are proposing to make a 1.75 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 2.8 percent market basket update, the proposed reduction of 0.8 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. As a result, we are proposing to make a 1.25 percent update to the hospital-specific rates.

Overall, hospitals would experience a 1.7 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 1.25 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 proposed FY 2019 MS–DRG relative weights would be 100 percent cost-based and 100 percent MS–DRGs. For FY 2019, the MS–DRGs are calculated using the FY 2017 MedPAR data grouped to the Version 36 (FY 2019) 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 0.997896 to the standardized amount. Hospital categories that generally treat more medical cases than surgical cases would experience a decrease in their payments under the relative weights. For example, rural hospitals would experience a 0.3 percent decrease in payments in part because rural hospitals tend to treat fewer surgical cases than medical cases. Conversely, teaching hospitals with more than 100 residents would experience an increase in payments of 0.1 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of updated wage data using FY 2015 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 2019 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 section III.A.2. of the preamble of 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 section III.A.2. of this proposed rule for a discussion of our proposed adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2019 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 2019 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2014 and before October 1, 2015. The estimated impact of the updated wage data using the FY 2015 cost report data and the 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 2018 wage index, based on FY 2014 wage data, the labor-related share of 68.3 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2019 pre-reclassification wage index based on FY 2015 wage data with the labor-related share of 68.3 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the Version 36 MS–DRG GROUPER constant. The proposed FY 2019 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 2019, we are proposing to calculate the 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 2019 wage budget neutrality factor is 1.001182, and the overall proposed payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2015 cost reports. Overall, the proposed 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 2018. 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 3,226 hospitals with wage data for both FYs 2018 and 2019, 1,445 or 44.8 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 2019 relative to FY 2018. Among urban hospitals, 10 would experience a decrease of 10 percent or more, and 6 urban hospitals would experience an increase of 10 percent or more. One hundred urban hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 5 would experience an increase of increase of 10 percent or more, and 2 would experience a decrease of 10 percent or more. Nine rural hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. However, 748 rural hospitals would experience increases or decreases of less than 5 percent, while 2,346 urban hospitals would experience increases or decreases of less than 5 percent. No urban hospitals and no rural hospitals would experience no change to their wage index. 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 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 proposed 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 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 2019 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	6	5
Increase greater than or equal to 5 percent and less than 10 percent	55	3
Increase or decrease less than 5 percent	2,346	748
Decrease greater than or equal to 5 percent and less than 10 percent	45	6
Decrease 10 percent or more	10	2
Unchanged	0	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 2019.

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 0.987084 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 1.4 percent. By region, all the rural hospital categories would experience increases 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 2019.

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 2018 IPPS/LTCH PPS final rules, and this FY 2019 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 received by rural hospitals in the same State. We would apply a uniform budget neutrality adjustment to the wage index. As discussed in section III.G. of the preamble of this proposed rule, we are not proposing to extend the imputed floor policy. Therefore, column 6 shows the effects of the proposed rural floor only.

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 2019 rural floor budget neutrality factor to be applied to the wage index of 0.994733, which would reduce wage indexes by 0.53 percent.

Column 5 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2019 wage index of providers before the proposed rural floor adjustment and the post-reclassification FY 2019 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floors. Because the provision is budget neutral, all other hospitals (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 nationally to their wage index.

We estimate that 255 hospitals would receive the rural floor in FY 2019. All IPPS hospitals in our model would have their wage index reduced by the proposed rural floor budget neutrality adjustment of 0.994733. We project that, in aggregate, rural hospitals would experience a −0.2 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 hospitals located in urban areas would experience no change in payments because proposed increases in payments by hospitals benefitting from the rural floor offset decreases in payments by 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 2.2 percent increase in payments primarily due to the application of the rural floor in Massachusetts. Thirty-five urban providers in Massachusetts are expected to receive the rural floor wage index value, including the proposed rural floor budget neutrality adjustment, increasing payments overall to Massachusetts by an estimated $49 million. We estimate that Massachusetts hospitals would receive approximately a 1.4 percent increase in IPPS payments due to the application of the proposed rural floor in FY 2019.

Urban Puerto Rico hospitals are expected to experience a 0 percent increase in payments as a result of the application of the proposed rural floor.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the rural floor with budget neutrality at the State level. Column 1 of the following table displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that would receive the rural floor wage index for FY 2019. Column 3 displays the percentage of total payments each State would receive or contribute to fund the rural floor with national budget neutrality. The column compares the proposed post-reclassification FY 2019 wage index of providers before the rural floor adjustment and the proposed post-reclassification FY 2019 wage index of providers with the rural floor adjustment. Column 4 displays the estimated payment amount that each State

would gain or lose due to the application of the rural floor with national budget neutrality.

PROPOSED FY 2019 IPPS ESTIMATED PAYMENTS DUE TO PROPOSED RURAL FLOOR WITH NATIONAL BUDGET NEUTRALITY

	Number of hospitals (1)	Number of hospitals that would receive the rural floor (2)	Proposed percent change in payments due to application of rural floor with budget neutrality (3)	Difference (in $ millions) (4)
Alabama	84	2	−0.3	−$4
Alaska	6	1	−0.2	0
Arizona	56	4	−0.2	−3
Arkansas	45	0	−0.3	−3
California	297	63	0.4	48
Colorado	46	9	0.6	8
Connecticut	30	17	5.5	90
Delaware	6	1	−0.3	−1
Washington, DC	7	0	−0.3	−2
Florida	168	8	−0.2	−17
Georgia	101	0	−0.3	−7
Hawaii	12	0	−0.2	−1
Idaho	14	0	−0.2	−1
Illinois	125	2	−0.3	−12
Indiana	85	0	−0.3	−7
Iowa	34	0	−0.3	−3
Kansas	51	0	−0.2	−2
Kentucky	64	0	−0.2	−4
Louisiana	90	0	−0.3	−4
Maine	17	0	−0.3	−1
Massachusetts	56	35	1.4	49
Michigan	94	0	−0.3	−12
Minnesota	49	0	−0.2	−5
Mississippi	59	0	−0.3	−3
Missouri	72	0	−0.2	−6
Montana	13	2	−0.2	−1
Nebraska	23	0	−0.2	−2
Nevada	22	3	0.4	4
New Hampshire	13	4	0.7	4
New Jersey	64	10	−0.4	−13
New Mexico	25	2	−0.2	−1
New York	149	18	−0.2	−16
North Carolina	84	0	−0.2	−9
North Dakota	6	5	1.2	4
Ohio	129	7	−0.2	−9
Oklahoma	79	1	−0.3	−4
Oregon	34	1	−0.2	−2
Pennsylvania	150	3	−0.3	−14
Puerto Rico	51	11	0.2	0
Rhode Island	11	10	−0.3	−1
South Carolina	54	6	0	−1
South Dakota	17	0	−0.2	−1
Tennessee	90	6	−0.3	−6
Texas	311	14	−0.2	−12
Utah	31	0	−0.2	−1
Vermont	6	0	−0.2	0
Virginia	74	1	−0.2	−5
Washington	48	4	−0.3	−6
West Virginia	29	2	−0.1	−1
Wisconsin	66	1	−0.3	−5
Wyoming	10	2	0.4	1

f. Effects of the Application of Proposed the 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 50 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 $61 million. Rural and urban hospitals located in the West North Central region would experience an increase in payments by 0.2 and 0.6 percent, respectively, 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 would 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 220 providers that would receive the out-migration wage adjustment in FY 2019. 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 and 0.2 percent increase in payments, respectively. (We note that there has been an increase in the number of RRCs as a result of the decision by the Court of Appeals for the Third Circuit in *Geisinger Community Medical Center* vs. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015) and subsequent regulatory changes (81 FR 23428).) This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the proposed out-migration increase would be approximately $36 million.

g. Effects of All Proposed FY 2019 Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2018 and FY 2019, resulting from all proposed changes reflected in this proposed rule for FY 2019. 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 2.1 percent for FY 2019 relative to FY 2018 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 7 includes the proposed annual hospital update of 1.25 percent to the national standardized amount. This proposed annual hospital update includes the proposed 2.8 percent market basket update, the proposed 0.8 percentage point reduction for the multifactor productivity adjustment, and the 0.75 percentage point reduction under section 3401 of the Affordable Care Act. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the +0.5 percent adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 1.25 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 2.1 percent increase in payments in FY 2019 relative to FY 2018. 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 2018 and FY 2019 in Column 7.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.1 percent for FY 2019. Hospitals in urban areas would experience a 2.1 percent increase in payments per discharge in FY 2019 compared to FY 2018. Hospital payments per discharge in rural areas are estimated to increase by 1.1 percent in FY 2019.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2019 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 2018 with the estimated proposed average payments per discharge for FY 2019, 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 2019 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2018 payment per discharge	Estimated proposed average FY 2019 payment per discharge	Proposed FY 2019 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,257	12,167	12,418	2.1
By Geographic Location	0	0	0	0
Urban hospitals	2,480	12,514	12,782	2.1
Large urban areas	1,310	13,078	13,356	2.1
Other urban areas	1,170	11,958	12,215	2.1
Rural hospitals	777	9,115	9,215	1.1
Bed Size (Urban)	0	0	0	0
0–99 beds	638	9,985	10,129	1.4
100–199 beds	763	10,422	10,598	1.7
200–299 beds	438	11,356	11,598	2.1
300–499 beds	427	12,635	12,902	2.1
500 or more beds	214	15,498	15,887	2.5
Bed Size (Rural)	0	0	0	0
0–49 beds	299	7,793	7,853	0.8
50–99 beds	279	8,630	8,717	1
100–149 beds	116	9,057	9,149	1
150–199 beds	44	9,611	9,712	1
200 or more beds	39	10,713	10,876	1.5

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2019 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2018 payment per discharge (2)	Estimated proposed average FY 2019 payment per discharge (3)	Proposed FY 2019 changes (4)
Urban by Region	0	0	0	0
New England	113	13,465	13,843	2.8
Middle Atlantic	310	14,104	14,369	1.9
South Atlantic	401	11,125	11,338	1.9
East North Central	385	11,828	12,055	1.9
East South Central	147	10,527	10,759	2.2
West North Central	158	12,238	12,487	2
West South Central	378	11,327	11,569	2.1
Mountain	163	12,940	13,090	1.2
Pacific	374	15,865	16,354	3.1
Puerto Rico	51	9,113	9,161	0.5
Rural by Region	0	0	0	0
New England	20	12,473	12,564	0.7
Middle Atlantic	53	9,046	9,155	1.2
South Atlantic	122	8,448	8,545	1.1
East North Central	114	9,332	9,428	1
East South Central	150	8,111	8,242	1.6
West North Central	94	9,900	9,969	0.7
West South Central	147	7,786	7,876	1.2
Mountain	54	10,907	10,993	0.8
Pacific	23	12,555	12,669	0.9
By Payment Classification	0	0	0	0
Urban hospitals	2,281	12,348	12,600	2
Large urban areas	1,325	13,065	13,343	2.1
Other urban areas	956	11,375	11,591	1.9
Rural areas	976	11,541	11,786	2.1
Teaching Status	0	0	0	0
Nonteaching	2,162	10,041	10,215	1.7
Fewer than 100 residents	846	11,630	11,856	1.9
100 or more residents	249	17,766	18,227	2.6
Urban DSH	0	0	0	0
Non-DSH	520	10,534	10,698	1.6
100 or more beds	1,483	12,717	12,983	2.1
Less than 100 beds	365	9,273	9,429	1.7
Rural DSH	0	0	0	0
SCH	258	9,830	9,899	0.7
RRC	367	12,346	12,653	2.5
100 or more beds	27	11,231	11,409	1.6
Less than 100 beds	127	7,161	7,298	1.9
Urban teaching and DSH	0	0	0	0
Both teaching and DSH	818	13,863	14,165	2.2
Teaching and no DSH	88	11,427	11,633	1.8
No teaching and DSH	1,030	10,372	10,565	1.9
No teaching and no DSH	345	9,983	10,138	1.6
Special Hospital Types	0	0	0	0
RRC	328	12,447	12,798	2.8
SCH	311	10,970	11,064	0.9
MDH	135	7,604	7,672	0.9
SCH and RRC	133	11,324	11,449	1.1
MDH and RRC	14	9,606	9,708	1.1
Type of Ownership	0	0	0	0
Voluntary	1,901	12,315	12,574	2.1
Proprietary	854	10,643	10,821	1.7
Government	501	13,411	13,710	2.2
Medicare Utilization as a Percent of Inpatient Days	0	0	0	0
0–25	546	15,419	15,705	1.9
25–50	2,121	12,023	12,287	2.2
50–65	477	9,798	9,922	1.3
Over 65	73	7,321	7,465	2
Invalid/Missing Data	39	9,508	9,867	3.8
FY 2019 Reclassifications by the Medicare Geographic Classification Review Board	0	0	0	0

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2019 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2018 payment per discharge (2)	Estimated proposed average FY 2019 payment per discharge (3)	Proposed FY 2019 changes (4)
All Reclassified Hospitals	911	12,230	12,514	2.3
Non-Reclassified Hospitals	2,346	12,137	12,371	1.9
Urban Hospitals Reclassified	633	12,818	13,134	2.5
Urban Nonreclassified Hospitals	1,795	12,382	12,632	2
Rural Hospitals Reclassified Full Year	278	9,469	9,596	1.3
Rural Nonreclassified Hospitals Full Year	452	8,662	8,723	0.7
All Section 401 Reclassified Hospitals:	246	13,340	13,694	2.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	8,579	8,665	1

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. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.H. of the preamble to this proposed rule, we discuss 15 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2019, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2018. 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.H.6. of the preamble of this proposed rule, we have not yet determined whether any of the 15 technologies for which we received applications for consideration for new technology add-on payments for FY 2019 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these 15 technologies for any potential new technology add-on payments for FY 2019. We note that if any of the 15 technologies are found to be eligible for new technology add-on payments for FY 2019, in the FY 2019 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2019.

In section II.H.5. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for Idarucizumab, GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), Edwards/Perceval Sutureless Valves, and Vistogard™ (Uridine Triacetate) for FY 2019 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 Defitelio® (Defibrotide), Ustekinumab (Stelara®) and Bezlotoxumab (Zinplava™) in FY 2019 because these technologies would still be considered new. We note that new technology add-on payments for each case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. 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 2019 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 2019 for the three technologies for which we are proposing to continue to make new technology add-on payments in FY 2019:

- Based on the applicant's estimate from FY 2017, we currently estimate that new technology add-on payments for Defitelio® would increase overall FY 2019 payments by $5,161,200 (maximum add-on payment of $75,900 * 68 patients).
- Based on the applicant's estimate from FY 2018, we currently estimate that new technology add-on payments for Ustekinumab (Stelara®) would increase overall FY 2019 payments by $400,800 (maximum add-on payment of $2,400 * 167 patients).
- Based on the applicant's estimate for FY 2018, we currently estimate that new technology add-on payments for Bezlotoxumab (Zinplava™) would increase overall FY 2019 payments by $2,857,600 (maximum add-on payment of $1,900 * 1,504 patients).

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. 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 2019, which are discussed in section II.F. of the preamble of this proposed rule, we are proposing additions to the list of MS–DRGs subject to the MS–DRG special payment policy. Column 4 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 2019.

In section IV.A.2.b. of the preamble of this proposed rule, we discuss our proposed conforming changes to the regulations at § 412.4(c) to reflect the amendments to section 1886(d)(5)(J) of the Act made by section 53109 of the Bipartisan Budget Act of 2018. Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J) of the Act to include discharges to hospice services provided by a hospice program as a ''qualified discharge'' under the postacute

care transfer policy, effective for discharges occurring on or after October 1, 2018. To implement this change, we are proposing that discharges using 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) would be subject to the postacute care transfer policy, effective for discharges occurring on or after October 1, 2018. Our actuaries estimate that this change in the postacute care transfer policy would generate an annual savings of approximately $240 million in Medicare payments in FY 2019, and up to $540 million annually by FY 2028.

3. Effects of Proposed Changes to Low-Volume Hospital Payment Adjustment Policy

In section IV.D. of the preamble of this proposed rule, we discuss the proposed changes to the low-volume hospital payment policy for FY 2019 to implement the provisions of section 50204 of the Bipartisan Budget Act of 2018. Specifically, for FY 2019, qualifying hospitals must have less than 3,800 combined Medicare and non-Medicare discharges (instead of 1,600 Medicare discharges) and must be located more than 15 road miles from another subsection (d) hospital. Section 50204 of the Bipartisan Budget Act of 2018 also modified the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. To implement these requirements, we are proposing that the low-volume hospital payment adjustment would be determined as follows:

- For low-volume hospitals with 500 or fewer total discharges during the fiscal year, an additional 25 percent for each Medicare discharge.
- For low-volume hospitals with total discharges during the fiscal year of more than 500 and fewer than 3,800, an additional percent calculated using the formula [(95/330) × (number of total discharges/13,200)] for each Medicare discharge.

Based upon the best available data at this time, we estimate the changes to the low-volume hospital payment adjustment policy that we are proposing to implement in accordance with section 50204 of the Bipartisan Budget Act of 2018 would increase Medicare payments by $72 million in FY 2019 as compared to FY 2018. More specifically, in FY 2019, we estimate that 622 providers would receive approximately $417 million compared to our estimate of 606 providers receiving approximately $345 million in FY 2018. These payment estimates were determined by identifying providers that, based on the best available data, are expected to qualify under the criteria that will apply in FY 2019 (that is, are located at least 15 miles from the nearest subsection (d) hospital and have less than 3,800 total discharges), and were determined from the same data used in developing the quantitative analyses of proposed changes in payments per case discussed previously in section I.G. of this Appendix A.

4. Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2019

As discussed in section IV.F. 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 additional statutory adjustments (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 2019 is $8,250,415,972.16. 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 67.51 percent. For FY 2018, the amount available to be distributed for uncompensated care was $6,766,695,163.56, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 58.01 percent. To calculate proposed Factor 3 for FY 2019, we used an average of data computed using Medicaid days from hospitals' 2013 cost reports from the HCRIS database as updated through February 15, 2018, uncompensated care costs from hospitals' 2014 and 2015 cost reports from the same extract of HCRIS, and SSI days from the FY 2016 SSI ratios. For each eligible hospital, with the exception of Puerto Rico hospitals, all-inclusive rate providers, and Indian Health Service and Tribal hospitals, we calculated a proposed Factor 3 using information from cost reports for FYs 2013, 2014, and 2015. To calculate Factor 3 for Puerto Rico hospitals, all-inclusive rate providers, and Indian Health Service and Tribal hospitals, we used data regarding low-income insured days for FY 2013. For a complete discussion of the proposed methodology for calculating Factor 3, we refer readers to section IV.F.4. of the preamble of this proposed rule.

To estimate the impact of the combined effect of proposed changes in 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 (UCP), we compared total UCP estimated in the FY 2018 IPPS/LTCH PPS final rule to total UCP estimated in this FY 2019 IPPS/LTCH PPS proposed rule. For FY 2018, for each hospital, we calculated 75 percent of the estimated amount that would have been paid as Medicare DSH payments in the absence of section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 58.01 percent and multiplied by a Factor 3 calculated, as described in the FY 2018 IPPS/LTCH PPS final rule. For FY 2019, we calculate 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 67.51 percent and multiplied by a Factor 3 calculated using the methodology described previously.

Our analysis included 2,485 hospitals that are projected to be eligible for DSH in FY 2019. It did not include hospitals that terminated their participation from the Medicare program as of January 1, 2018, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. Hospitals participating in the Rural Community Hospital Demonstration Program were inadvertently included in the current impact analysis, but will be excluded in the final rule, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. Roughly $6.6 million in total uncompensated care payments was estimated for 13 of the 30 participating hospitals. However, in the final rule, uncompensated care payments will be distributed only to eligible hospitals projected to receive Medicare DSH payments. In addition, low-income insured days and uncompensated care costs from merged or acquired hospitals were combined into 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 2019, by hospital characteristic, is presented in the following table.

MODELED UNCOMPENSATED CARE PAYMENTS FOR ESTIMATED FY 2019 DSHS BY HOSPITAL TYPE: MODEL UCP $ (IN MILLIONS) FROM FY 2018 TO FY 2019

	Number of estimated DSHs	FY 2018 final rule CN estimated UCP $ (in millions)	FY 2019 proposed rule estimated UCP $ (in millions)	Dollar difference: FY 2019–FY 2018 (in millions)	Percent change **
	(1)	(2)	(3)	(4)	(5)
Total	2,485	$6,767	$8,250	$1,484	21.93
By Geographic Location:					
Urban Hospitals	1,962	6,422	7,793	1,371	21.35
Large Urban Areas	1,050	3,847	4,624	777	20.20
Other Urban Areas	912	2,575	3,169	594	23.06
Rural Hospitals	522	345	457	112	32.50
Bed Size (Urban):					
0 to 99 Beds	351	177	246	68	38.53
100 to 249 Beds	860	1,519	1,862	343	22.59
250+ Beds	751	4,726	5,685	959	20.30
Bed Size (Rural):					
0 to 99 Beds	388	164	232	67	41.01
100 to 249 Beds	121	146	185	39	26.77
250+ Beds	13	34	40	6	16.21
Urban by Region:					
New England	92	259	289	30	11.65
Middle Atlantic	247	1,004	1,057	53	5.30
South Atlantic	316	1,343	1,829	486	36.17
East North Central	325	864	1,019	155	17.96
East South Central	134	389	464	75	19.36
West North Central	104	312	379	67	21.46
West South Central	257	981	1,396	415	42.28
Mountain	125	313	365	52	16.58
Pacific	320	874	894	20	2.29
Puerto Rico	42	82	99	17	21.23
Rural by Region:					
New England	12	14	18	4	30.09
Middle Atlantic	26	19	20	1	3.55
South Atlantic	90	79	109	30	38.63
East North Central	72	40	55	15	37.19
East South Central	135	93	101	8	8.80
West North Central	39	16	32	16	99.17
West South Central	112	66	91	25	38.01
Mountain	29	14	24	10	73.48
Pacific	7	4	6	3	67.46
By Payment Classification:					
Urban Hospitals	1,879	5,917	7,245	1,328	22.44
Large Urban Areas	1,062	3,855	4,634	780	20.23
Other Urban Areas	817	2,062	2,610	548	26.59
Rural Hospitals	605	850	1,005	155	18.25
Teaching Status:					
Nonteaching	1,545	2,020	2,522	503	24.90
Fewer than 100 residents	695	2,246	2,695	448	19.96
100 or more residents	244	2,501	3,033	532	21.27
Type of Ownership:					
Voluntary	1,468	4,137	4,813	676	16.35
Proprietary	566	1,015	1,258	243	23.98
Government	450	1,615	2,179	564	34.93
Medicare Utilization Percent:					
0 to 25	470	2,255	2,663	408	18.07
25 to 50	1,691	4,290	5,299	1,009	23.53
50 to 65	281	215	279	63	29.42
Greater than 65	39	7	9	3	40.26

Source: Dobson √ DaVanzo analysis of 2013–2015 Hospital Cost Reports.

* Dollar UCP 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 $6,767 million in FY 2018 and $8,250 million in FY 2018.

** Percentage change is determined as the difference between Medicare UCP payments modeled for the FY 2019 IPPS/LTCH PPS proposed rule (column 3) and Medicare UCP payments modeled for the FY 2018 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare UCP payments modeled for the FY 2018 final rule correction notice (column 2) times 100 percent.

*** Hospitals with Missing or Unknown Medicare Utilization are not shown in table.

Changes in projected FY 2019 uncompensated care payments from payments in FY 2018 are driven by increases in Factor 1 and Factor 2, as well as by an increase in the number of hospitals eligible to receive DSH in FY 2019 relative to FY 2018. Factor 1 has increased from $11.665 billion to $12.221 billion, and the percent change in the percent of individuals who are

uninsured (Factor 2) has increased from 58.01 percent to 67.51 percent. Based on the proposed increases in these two factors, the proposed impact analysis found that, across all projected DSH eligible hospitals, FY 2019 uncompensated care payments are estimated at approximately $8.250 billion, or an increase of approximately 21.9 percent from FY 2018 uncompensated care payments (approximately $6.767 billion). While these proposed changes would result in a net increase in the amount available to be distributed in uncompensated care payments, the projected payment increases vary by hospital type. This redistribution of uncompensated care payments is caused by changes in Factor 3.

As seen in the above table, percent increases smaller than 21.93 percent indicate that hospitals within the specified category are projected to experience a smaller increase in uncompensated care payments, on average, compared to the universe of projected FY 2019 DSH hospitals. Conversely, percent increases that are greater than 21.93 percent indicate a hospital type is projected to have a larger increase than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's number of Medicaid days and SSI days, as well as its uncompensated care costs as reported in the Worksheet S–10, used in the Factor 3 computation.

Many rural hospitals are projected to experience a larger increase in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 32.50 percent increase in uncompensated care payments, while urban hospitals are projected to receive a 21.35 percent increase in uncompensated care payments.

By bed size, smaller hospitals are projected to receive larger increases in uncompensated care payments than larger hospitals, in both rural and urban settings. Rural hospitals with 0–99 beds are projected to receive a 41.01 percent payment increase, and rural hospitals with 100–249 beds are projected to see a 26.77 percent increase. Larger rural hospitals with 250+ beds are projected to experience a 16.21 percent payment increase, which is smaller than the overall average. This trend is consistent with urban hospitals, in which the smallest urban hospitals (0–99 beds) are projected to receive an increase in uncompensated care payments of 38.53 percent. Urban hospitals with 100–250 beds are projected to receive an increase of 22.59 percent, which is consistent with the overall average, while larger urban hospitals with and 250+ beds are projected to receive a 20.30 percent increase in uncompensated care payments, which is somewhat smaller than the overall average but larger than the increase projected for their rural counterparts.

By region, rural hospitals in the West North Central region are expected to receive a large increase in uncompensated care payments, as are rural hospitals in the Mountain, Pacific, South Atlantic, West South Central, East North Central, and New England regions. Rural hospitals in the Middle Atlantic and East South Central regions are projected to receive smaller than average payment increases. Regionally, urban hospitals are projected to receive a wide range of payment changes. Small increases in uncompensated care payments are projected in the Pacific and Middle Atlantic regions. Smaller than average increases in payments are also projected in the New England, Mountain, East North Central, and East South Central regions. Hospitals in the South Atlantic and West South Central regions are projected to receive a larger than average increase in uncompensated payments, while the projected increase in the West North Central region and in Puerto Rico is generally consistent with the overall average increase of 21.93 percent.

Nonteaching hospitals are projected to receive a larger than average payment increase of 24.90 percent. Teaching hospitals with fewer than 100 residents are projected to receive payment increases of 19.96 percent, which is slightly below average, while those teaching hospitals with 100+ residents have a projected payment increase of 21.27 percent, consistent with the overall average. Government and proprietary hospitals are projected to receive larger than average increases (34.93 percent and 23.98 percent, respectively), while voluntary hospitals are expected to receive increases lower than the overall average at 16.35 percent. Hospitals with 0 to 25 percent Medicare utilization are projected to receive increases in uncompensated care payments slightly below the overall average, while all other hospitals are projected to receive larger increases.

5. Effects of Proposed Reduction Under the Hospital Readmissions Reduction Program for FY 2019

In section IV.H. of the preamble of this proposed rule, we discuss proposed requirements for the 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. The table and analysis below illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology, as outlined in this FY 2019 IPPS/LTCH PPS proposed rule. In this table, we are presenting the estimated impact of the FY 2019 Hospital Readmissions Reduction Program on hospitals by hospital characteristic.

The table presents results of hospitals stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2013 and June 30, 2016 (that is, the FY 2018 Hospital Readmissions Reduction Program performance period). Hospitals' performance on the 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. To analyze the results by hospital characteristic, we used the FY 2018 Inpatient Prospective Payment System (IPPS) Final Rule Impact File.

This table includes 3,064 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, 2013 and June 30, 2016. The second column in the table indicates the total number of penalty eligible non-Maryland hospitals (that is, have an estimated payment adjustment factor less than 1) with available data for each characteristic.

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty for each characteristic. For example, with regards to teaching status, 81.90 percent of eligible hospitals characterized as non-teaching hospitals would be penalized. Among teaching hospitals, 90.05 percent of eligible hospitals with fewer than 100 residents and 96.37 percent of eligible hospitals with 100 or more residents would be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristics. The table shows the share of payment adjustments as a percentage of all base operating DRG payments for 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, 2015 and September 30, 2016 (FY 2016). 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 proportion of total base operating DRG payments allows us to account 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.

ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENT FOR FY 2019 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	3,064	2,610	85.18	0.70
By Geographic Location (n=3,064): [e]				
Urban hospitals	2,291	1,991	86.91	0.69
1–99 beds	530	375	70.75	0.80
100–199 beds	711	645	90.72	0.81
200–299 beds	419	387	92.36	0.77
300–399 beds	273	255	93.41	0.69
400–499 beds	145	137	94.48	0.55
500 or more beds	213	192	90.14	0.62
Rural hospitals	773	619	80.08	0.71
1–49 beds	292	208	71.23	0.61
50–99 beds	283	231	81.63	0.67
100–149 beds	115	104	90.43	0.76
150–199 beds	44	40	90.91	0.59
200 or more beds	39	36	92.31	0.86
By Teaching Status [f] (n=3,064):				
Non-teaching	2,022	1,656	81.90	0.80
Fewer than 100 Residents	794	715	90.05	0.70
100 or more Residents	248	239	96.37	0.53
By Ownership Type (n=3,064):				
Government	481	397	82.54	0.58
Proprietary	768	616	80.21	0.96
Voluntary	1,815	1,597	87.99	0.66
By Safety-net Status [g] (n=3,064):				
Safety-net hospitals	619	541	87.40	0.57
Non-safety-net hospitals	2,445	2,069	84.62	0.73
By DSH Patient Percentage [h] (n=3,064):				
0–24	1,246	1,021	81.94	0.78
25–49	1,452	1,269	87.40	0.66
50–64	200	182	91.00	0.64
65 and over	166	138	83.13	0.59
By Medicare Cost Report (MCR) Percent: [i] (n=3,061):				
0–24	433	368	84.99	0.46
25–49	2,100	1,819	86.62	0.71
50–64	468	381	81.41	0.89
65 and over	60	41	68.33	1.25
By Region (n=3,064):				
New England	129	114	88.37	0.82
Middle Atlantic	352	327	92.90	0.85
South Atlantic	511	469	91.78	0.84
East North Central	480	417	86.88	0.65
East South Central	288	258	89.58	0.87
West North Central	247	196	79.35	0.46
West South Central	476	373	78.36	0.63
Mountain	218	163	74.77	0.56
Pacific	363	293	80.72	0.42

Source: Results based on July 1, 2013 through June 30, 2016 discharges among subsection (d) and Maryland hospitals only. 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 since Maryland hospitals are not eligible for a penalty under the program. Hospitals are stratified into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the 3-year FY 2018 performance period. Hospital characteristics are from the FY 2018 Hospital Inpatient Prospective Payment System (IPPS) Final Rule Impact File.

[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 (*i.e.,* 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.

[d] The penalty as a share of payments 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 hospitals with that characteristic. MedPAR data from October 1, 2015 through September 30, 2016 (FY 2016), are used to calculate the total base operating DRG payments, which are used to estimate total penalties.

[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: Geographic location, bed size, teaching status, ownership type, safety-net status, DSH patient percentage, and region (n=3,064). Not all hospitals had data for MCR percent (n=3,061).

[f] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if they are in the top DSH quintile.

[h] DSH [Disproportionate Share Hospital] 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 [Medicare Cost Report] percent is the percentage of total inpatient stays from Medicare patients.

6. Effects of Proposed Changes Under the FY 2019 Hospital Value-Based Purchasing (VBP) Program

a. Effects of Proposed Changes for FY 2019

In section IV.I. 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 2019 through a reduction to the FY 2019 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 2019 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.I.1.b. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2019 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.9 billion. This estimated available pool for FY 2019 is based on the historical pool of hospitals that were eligible to participate in the FY 2018 program year and the payment information from the December 2017 update to the FY 2017 MedPAR file.

The proposed estimated impacts of the FY 2019 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2018 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 2017 update to the FY 2017 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 2019 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is higher than the number of hospitals that would receive a decrease. On average, urban hospitals in the West North Central region and rural hospitals in Mountain region would have the highest positive percent change in base operating DRG. Urban Middle Atlantic, urban South Atlantic, and urban East South Central regions would experience an average decrease in base operating DRG. All other regions, both urban and rural, would have an average increase in base operating DRG.

As DSH percent increases, the average percent change in base operating DRG would decrease. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the percent change in base operating DRG would tend to increase. On average, teaching hospitals would have a decrease in base operating DRG, while non-teaching hospitals would have an increase in base operating DRG.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2019 HOSPITAL VBP PROGRAM

	Number of hospitals	Average net percentage payment adjustment
By Geographic Location:		
All Hospitals	2,808	0.163
Large Urban	1,146	0.067
Other Urban	994	0.070
Rural Area	668	0.465
Urban hospitals	*2,140*	*0.068*
0–99 beds	375	0.475
100–199 beds	708	0.120
200–299 beds	429	−0.037
300–499 beds	416	−0.185
500 or more beds	212	−0.117
Rural hospitals	*668*	*0.465*
0–49 beds	201	0.675
50–99 beds	272	0.526
100–149 beds	114	0.306
150–199 beds	43	0.048
200 or more beds	38	−0.125
By Region:		
Urban By Region	2,140	0.068
New England	107	0.191
Middle Atlantic	288	−0.101
South Atlantic	376	−0.024
East North Central	348	0.178
East South Central	131	−0.101
West North Central	137	0.315
West South Central	265	0.011
Mountain	144	0.027
Pacific	344	0.189
Rural By Region	668	0.465
New England	20	0.739
Middle Atlantic	51	0.397
South Atlantic	108	0.489
East North Central	108	0.489
East South Central	123	0.214
West North Central	82	0.628
West South Central	109	0.349
Mountain	46	0.785
Pacific	21	0.562
By MCR Percent:		
0–25	434	0.122

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2019 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average net percentage payment adjustment
25–50	1,958	0.152
50–65	389	0.250
Over 65	27	0.350
Missing	.....	.....
By DSH Percent:		
0–25	1,082	0.254
25–50	1,381	0.126
50–65	196	0.005
Over 65	149	0.046
By Teaching Status:		
Non-Teaching	1,763	0.278
Teaching	1,045	−0.032

Actual FY 2019 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2019 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2018 program year will be used for the updated impact analysis in that final rule.

b. Effects of Proposed Domain Weighting and Alternative Considered Beginning With the FY 2021 Program Year

In section IV.I.4.b. of the preamble of this proposed rule, we discuss our proposed changes to the Hospital VBP Program domain weighting beginning with the FY 2021 program year. We note that we are not proposing to make any changes to the domain weighting for the FY 2019 or FY 2020 program years. The estimated impacts of the proposed domain weighting and alternative considered for three domains beginning with the FY 2021 program year, by hospital characteristic found in the table below, are based on historical TPSs. This analysis uses the same data set as the proposed estimated impacts for the FY 2019 program year above, and is intended to expand upon the analysis of the proposed domain weighting and alternative considered discussed in section IV.I.4.b. of the preamble of this proposed rule.

This impact analysis shows that under the proposed domain weighting to increase the Clinical Outcomes domain (proposed domain name; previously referred to as the Clinical Care domain) from 25 percent to 50 percent of each hospital's TPS, we estimate that on average, urban hospitals in the East South Central region and rural hospitals in New England region would have the highest positive percent change in base operating DRG. We estimate that four of the urban regions would have a decrease in base operating DRG, on average. We estimate that rural hospitals in East South Central and West South Central would have a decrease in base operating DRG, on average, while rural hospitals in the other regions would have an increase. We estimate that hospitals with a DSH percent 0–25 would have a positive percent change in base operating DRG, while hospitals with higher DSH percentages would have negative percent change in base operating DRG, on average. We estimate that hospitals with MCR percent over 65 would have a positive percent change in base operating DRG, while hospitals with lower MCR percentages would have negative percent change in base operating DRG, on average. We estimate that both teaching and non-teaching hospitals would have a negative percent change in base operating DRG.

Under the alternative domain weighting we considered of equally weighting each of the three domains to constitute one-third of each hospital's TPS, we estimate that rural hospitals in New England region would have the highest positive percent change in base operating DRG, with all rural hospitals estimated to have a positive percent change in base operating DRG. We estimate that on average urban hospitals in four regions would have a positive percent change in base operating DRG, while urban hospitals in five of the regions would have a negative percent change in base operating DRG. We estimate that hospitals with a DSH percent of 0–25 and 25–50 would have a positive percent change in base operating DRG, while hospitals with higher DSH percentages would have negative percent change in base operating DRG, on average. We estimate that hospitals with MCR percent 0–25 would have a negative percent change in base operating DRG, while hospitals with higher MCR percentages would have positive percent change in base operating DRG, on average. We estimate that teaching hospitals would have a negative percent change in base operating DRG, on average, while nonteaching hospitals would have a positive percent change in base operating DRG.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM PROPOSED AND ALTERNATIVE DOMAIN WEIGHTING CONSIDERED FOR THREE DOMAINS BEGINNING WITH THE FY 2021 HOSPITAL VBP PROGRAM

	Number of hospitals	Average percentage payment adjustment (proposed domain weighting)	Average percentage payment adjustment (alternative domain weighting)
By Geographic Location:			
All Hospitals	2,701	−0.071	0.059
Large Urban	1,087	−0.019	−0.015
Other Urban	963	−0.152	−0.032
Rural Area	651	−0.040	−0.318
Urban hospitals	2,050	−0.081	−0.023
0–99 beds	341	0.051	0.379
100–199 beds	682	−0.106	−0.040
200–299 beds	407	−0.118	−0.120
300–499 beds	409	−0.186	−0.233

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM PROPOSED AND ALTERNATIVE DOMAIN WEIGHTING CONSIDERED FOR THREE DOMAINS BEGINNING WITH THE FY 2021 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average percentage payment adjustment (proposed domain weighting)	Average percentage payment adjustment (alternative domain weighting)
500 or more beds	211	0.058	−0.026
Rural hospitals	651	−0.040	−0.318
0–49 beds	188	0.044	0.573
50–99 beds	268	0.024	0.379
100–149 beds	114	−0.155	0.105
150–199 beds	43	−0.298	−0.148
200 or more beds	38	−0.262	−0.203
By Region:			
Urban By Region	2,050	−0.081	−0.023
New England	105	0.203	0.172
Middle Atlantic	284	−0.166	−0.191
South Atlantic	373	−0.178	−0.119
East North Central	342	0.061	0.109
East South Central	127	0.384	−0.248
West North Central	133	0.127	0.344
West South Central	248	−0.189	−0.148
Mountain	137	−0.147	−0.074
Pacific	301	0.013	0.093
Rural By Region	651	−0.040	0.318
New England	19	0.317	0.661
Middle Atlantic	51	0.066	0.314
South Atlantic	106	0.039	0.379
East North Central	108	0.011	0.398
East South Central	122	−0.283	0.031
West North Central	82	0.088	0.557
West South Central	102	−0.219	0.077
Mountain	40	0.185	0.658
Pacific	21	0.079	0.563
By MCR Percent:			
0–25	350	−0.189	−0.119
25–50	1,937	−0.063	0.058
50–65	387	−0.029	0.188
Over 65	27	0.238	0.579
Missing	.....	.....	.....
By DSH Percent:			
0–25	1,031	0.021	0.182
25–50	1,359	−0.127	0.012
50–65	185	−0.184	−0.156
Over 65	126	−0.058	−0.119
By Teaching Status:			
Non-Teaching	1,702	−0.056	0.151
Teaching	999	−0.097	−0.098

7. Effects of Proposed Changes to the HAC Reduction Program for FY 2019

In section IV.J. 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 adopt any new measures into the HAC Reduction Program. However, the Hospital IQR Program is proposing to remove the claims-based Patient Safety and Adverse Events Composite (PSI–90) and five NHSN HAI measures. These measures had been previously adopted for, and will remain in, the HAC Reduction Program. We are proposing to begin validation of these HAI measures under the HAC Reduction Program beginning in FY 2020.

We note the burden associated with collecting and submitting data via the NHSN system is captured under a separate OMB control number, 0920–0666, and therefore will not impact our burden estimates. We anticipate the proposed removal of the NHSN HAI measures from the Hospital IQR Program will result in a net burden decrease to the Hospital IQR Program, but will result in an off-setting net burden increase to the HAC Reduction Program because hospitals selected for validation will continue to be required to submit validation templates for the HAI measures. Therefore, if the proposals found in section VIII.A.5.b.(1) and IV.J.4.e. of the preamble of this proposed rule to remove HAI chart-abstracted measures from the Hospital IQR Program and adopt validation process for the HAC Reduction Program are finalized, then we anticipate a shift in burden associated with this data validation effort to the HAC Reduction Program beginning in FY 2020. We discuss the associated burden hours in section XV.B.7. of this proposed rule, and note the burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938—NEW.

The table below presents the estimated proportion of hospitals in the FY 2019 worst-performing quartile of the Total HAC Scores by hospital characteristic. These FY 2019 HAC Reduction Program results were calculated using the Winsorized z-score methodology finalized in the 2017 IPPS/LTCH PPS final rule (80 FR 57022 through 57025). Each hospital's Total HAC Score was calculated as the weighted average of the hospital's Domain 1 score (15 percent) and

Domain 2 score (85 percent). Non-Maryland hospitals with a Total HAC Score above the 75th percentile Total HAC Score were identified as being in the worst-performing quartile.

We used the modified Recalibrated Patient Safety Indicator (PSI) 90 Composite measure results based on Medicare fee-for-service (FFS) discharges from October 1, 2015 through June 30, 2017 and ICD–10 recalibrated version 8.0 of the CMS PSI software to estimate the impact of the FY 2019 HAC Reduction Program. For the 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) measure results, we used standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2015 through December 31, 2016.[403]

To analyze the results by hospital characteristic, we used the FY 2018 Final Rule Impact File. This table includes 3,216 non-Maryland hospitals with an FY 2019 Total HAC Score. Of these, 3,201 hospitals had information for geographic location and bed size, Disproportionate Share Hospital (DSH) percent, teaching status, ownership status, and safety-net status;[404] 3,188 had information for Medicare Cost Report (MCR) percent; and 3,214 had information for their geographic region. Maryland hospitals and hospitals without a Total HAC Score are not included in the table below.

The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have a Total HAC Score for the FY 2019 HAC Reduction Program. For example, with regard to teaching status, 2,131 hospitals are characterized as non-teaching hospitals, 822 are characterized as teaching hospitals with fewer than 100 residents, and 248 are characterized as teaching hospitals with at least 100 residents. This only represents a total of 3,201 hospitals because the other 15 hospitals have missing data for teaching status. 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 2019 HAC Reduction Program. For example, with regard to teaching status, 475 out of 2,131 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 199 out of 822 hospitals with fewer than 100 residents and 116 out of 248 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 would receive a payment reduction under the FY 2019 HAC Reduction Program. For example, 22.3 percent of the 2,131 hospitals characterized as non-teaching hospitals, 24.2 percent of the 822 teaching hospitals with fewer than 100 residents, and 46.8 percent of the 248 hospitals with 100 or more residents would be subject to a payment reduction.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2019 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]	3,216	804	25.0
By Geographic Location (n=3,201): [d]			
Urban hospitals	2,415	630	26.1
1–99 beds	624	125	20.0
100–199 beds	724	190	26.2
200–299 beds	432	116	26.9
300–399 beds	275	77	28.0
400–499 beds	147	48	32.7
500 or more beds	213	74	34.7
Rural hospitals	786	160	20.4
1–49 beds	304	56	18.4
50–99 beds	283	68	24.0
100–149 beds	116	21	18.1
150–199 beds	44	8	18.2
200 or more beds	39	7	17.9
By Safety-Net Status [e] (n=3,201):			
Non-safety net	2,557	570	22.3
Safety-net	644	220	34.2
By DSH Percent [f] (n=3,201):			
0–24	1,340	285	21.3
25–49	1,472	358	24.3
50–64	210	76	36.2
65 and over	179	71	39.7
By Teaching Status [g] (n=3,201):			
Non-teaching	2,131	475	22.3
Fewer than 100 residents	822	199	24.2
100 or more residents	248	116	46.8
By Ownership (n=3,201):			
Voluntary	1,866	474	25.4
Proprietary	838	166	19.8
Government	497	150	30.2
By MCR Percent [h] (n=3,188):			
0–24	515	148	28.7
25–49	2,128	513	24.1
50–64	471	109	23.1

[403] Updated FY 2019 data for the CDC NHSN measures (1/1/2016 through 12/31/2017) was not available at the time of publishing this proposed rule.

[404] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2019 HAC REDUCTION PROGRAM—Continued

[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]
65 and over	74	15	20.3
By Region (n=3,214): [i]			
New England	133	36	27.1
Mid-Atlantic	364	119	32.7
South Atlantic	524	140	26.7
East North Central	497	101	20.3
East South Central	299	75	25.1
West North Central	256	50	19.5
West South Central	516	98	19.0
Mountain	227	61	26.9
Pacific	398	122	30.7

Source: FY 2019 HAC Reduction Program Proposed Rule Results are based on Recalibrated PSI 90 Composite data from October 2015 through June 2017 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2015 through December 2016. Hospital Characteristics are based on the FY 2018 Hospital Inpatient Prospective Payment System (IPPS) 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 2019 Total HAC Score (N=3,216). 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, Disproportionate Share Hospital (DSH) percent, teaching status, and ownership status (n=3,201).

[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 IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for MCR percent (n=3,188).

[i] Not all hospitals had data for Region (n=3,214).

8. Effects of Proposed Changes Relating to Medicare GME Agreements for New Urban Teaching Hospitals

In section IV.K.2. of the preamble of this proposed rule, we discuss our proposal to provide new urban teaching hospitals with greater flexibility under the regulation governing Medicare GME affiliation agreements. Currently, if a new urban teaching hospital participates in a Medicare GME affiliation agreement, it can only receive an increase in its cap(s) as part of that agreement. That is, if a hospital with IME or direct GME FTE resident caps established under § 412.105(f)(1)(iv) or § 413.79(c)(2), or both, based on training occurring in 1996, is part of the Medicare GME affiliated group, § 413.79(e)(1)(iv) provides that the new urban teaching hospital(s) would only be permitted to receive in increase in its cap(s). We are proposing to revise the regulation to specify that, effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, a new urban teaching hospital (that is, a hospital that qualifies for an adjustment under § 412.105(f)(1)(vii) or § 413.79(e)(1), or both) may participate in a Medicare GME affiliated group composed solely of new urban teaching hospitals and be eligible to receive a decrease to its FTE caps as a result of participation in that affiliated group. Rather than create new FTE cap slots to cross train residents, Medicare GME affiliation agreements use existing cap slots to allow residents to rotate to various hospitals. Because Medicare GME affiliation agreements use existing FTE cap slots, we do not anticipate any significant cost impact associated with this proposal.

9. Effects of Proposed Implementation of the Rural Community Hospital Demonstration Program in FY 2019

In section IV.L. of the preamble of this proposed rule for FY 2019, 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. 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. However, by the time of the FY 2018 IPPS/LTCH PPS final rule, we had not been able to verify which among the previously participating hospitals would be continuing participation, and thus were not able to estimate the costs of the demonstration for that year's final rule. We stated in the final rule that we would instead include the estimated costs of the demonstration for all participating hospitals for FY 2018, along with those for FY 2019, in the budget neutrality offset amount for the FY 2019 proposed and final rules.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act have elected to continue in the second 5-year extension period, while 13 additional hospitals have been selected to participate. Each of these newly participating hospitals will begin its 5-year period of participation effective the start of the first cost reporting period on or after October 1, 2017. Thus, 30 hospitals are participating in the demonstration during FY 2018.

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.

Because we were unable to confirm the hospitals that would be participating in the second extension period in time for including the estimates of the cost of the demonstration in FY 2018 in the FY 2018 final rule, we indicated that we will include this estimate in the FY 2019 IPPS/LTCH proposed and final rules. For this proposed rule, the resulting amounts applicable to FYs 2018 and 2019, respectively, are $33,254,247 and $78,409,842, which we are proposing to include in the budget neutrality offset adjustment for FY 2019. These estimated amounts are based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and proposed update factors for cost, payment, and volume. If updated data become available prior to the FY 2019 IPPS/LTCH PPS final rule, we will use them to the extent appropriate to estimate the costs of the demonstration program. In addition, we will determine the costs of the demonstration for the previously participating hospitals for the period from when their period of performance ended for the first 5-year extension period and the start of the cost report year in FY 2018 when finalized cost reports for this period are available. We will include these costs for the demonstration in future rulemaking.

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 2010 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. Currently, finalized cost reports are now available for the 16 hospitals that completed a cost reporting period beginning in FY 2011 according to the demonstration cost-based payment methodology, as well as for the 23 hospitals that completed such a cost reporting period beginning in FY 2012. The actual costs of the demonstration for FY 2011 as determined from the finalized cost reports fell short of the estimated amount that was finalized in the FY 2011 IPPS/LTCH PPS final rule for FY 2011 by $29,971,829; the actual costs of the demonstration for FY 2012 fell short of the amount that was finalized in the FY 2012 final rule by $8,500,373.

We note that, for this proposed rule, the amounts identified for the actual costs of the demonstration for each of FYs 2011 and 2012 (determined from current finalized cost reports) are less than the amounts that were identified in the final rule for each these fiscal years. Therefore, in keeping with previous policy finalized in similar situations when the costs of the demonstration fell short of the amount estimated in the corresponding year's final rule, we will be including this component as a negative adjustment to the budget neutrality offset amount for the current fiscal year.

Therefore, for FY 2019, the total amount that we are proposing to apply to the national IPPS rates is $73,191,887. If updated data become available prior to the FY 2019 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine the budget neutrality offset amount for FY 2019. Furthermore, if the needed cost reports are available in time for the FY 2019 IPPS/LTCH PPS final rule, we will also identify the difference between the total cost of the demonstration based on finalized FY 2013 cost reports and the estimate of the costs of the demonstration for that year, and incorporate that amount into the budget neutrality offset amount for FY 2019. In addition, when finalized cost reports for FYs 2014 through 2016 are available, we will include the difference between the actual costs as reflected on these cost reports and the amounts included in the budget neutrality offset amounts for these fiscal years in a future final rule.

10. Effect of Proposed Revision of the Hospital Inpatient Admission Order Documentation Requirements

In section IV.M. of the preamble of this proposed rule, we discuss our proposal to revise the admission order documentation requirements. Specifically, we are proposing to revise the inpatient admission order policy to no longer require the presence of a written inpatient admission order in the medical record as a specific condition of Medicare Part A payment. Our actuaries estimate that any increase in Medicare payments due to the proposed change would be negligible, given the anticipated low volume of claims that would be payable under this proposed policy that would not have been paid under the current policy.

11. Effect of Proposed Policy Changes Relating to Satellite Facilities and Excluded Units

In section VI.B. of the preamble of this proposed rule, we discuss our proposal to revise the regulations applicable to satellite facilities so that the separateness and control requirements would only apply to IPPS-excluded satellite facilities that are co-located with IPPS hospitals beginning in FY 2019. This proposed policy change is premised on the belief that the policy concerns that underlie our existing satellite facility regulations (that is, inappropriate patient shifting and hospitals acting as illegal de facto units) are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other but not IPPS hospitals, in large part due to the payment system changes that have occurred over the intervening years for IPPS-excluded hospitals, the requirements in the hospital conditions of participation (CoPs) (which are still present regardless of these proposed changes), and because such changes would be consistent with the revisions to our HwH policy that were finalized in the FY 2018 IPPS/LTCH PPS final rule, which was estimated to have a *de minimus* effect on Medicare payments due to the administrative nature of the changes. We also are proposing to revise our regulations to allow IPPS-excluded hospitals to operate as IPPS-excluded units, as discussed in section VI.C. of the preamble to this proposed rule, effective with cost reporting periods beginning on or after October 1, 2019. We believe that this proposal is also consistent with the revisions to our HwH policy that were finalized in the FY 2018 IPPS/LTCH PPS final rule and the proposed changes to the satellite regulation discussed previously. We do not expect any significant payment impact as a result of either of these proposed policies because these policies are primarily administrative in nature and are not expected to result in additional Medicare expenditures that would have been made, regardless of our changes, because IPPS hospital co-location is already allowed under existing regulations.

12. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.D.2. of the preamble of this proposed rule, 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 are being implemented with the goal of increasing access to care with no net increase in costs. (We initially addressed

this demonstration in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065).)

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, CMS 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 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.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, in the event the demonstration is found not to have been budget neutral, we plan to recoup any excess costs over a period of three cost report periods, beginning in CY 2020. Therefore, this policy has no impact for any national payment system for FY 2019.

13. Effects of Proposed Revisions of the Supporting Documentation Required for Submission of an Acceptable Medicare Cost Report

In section IX.B.1. of the preamble of this proposed rule, we are proposing to incorporate the Provider Cost Reimbursement Questionnaire, Form CMS–339 (OMB No. 0938–0301), into the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS–216 (OMB No. 0938–0102), which would complete our incorporation of the Form CMS–339 into all Medicare cost reports. We also are proposing to update § 413.24(f)(5)(i) to reflect that an acceptable cost report will no longer require the provider to separately submit a Provider Cost Reimbursement Questionnaire, Form CMS–339, by removing the reference to the questionnaire. There are 58 OPOs and 47 histocompatibility laboratories. This proposal would not require additional data collection from OPOs or histocompatibility laboratories. This proposal would benefit OPOs and histocompatibility laboratories because they would no longer be required to complete and submit the Form CMS–339 as a separate form independent of the Medicare cost report in order to have an acceptable cost report submission under § 413.24(f)(5)(i). As discussed in detail in section IX.B.10. of the preamble of this proposed rule, this proposal would decrease overall costs to the 58 OPOs and 47 histocompatibility laboratories by $11,178.52.

In section IX.B.2. of the preamble of this proposed rule, we also are proposing that, effective for cost reports filed on or after October 1, 2018, a cost report is rejected for teaching hospitals for lack of supporting documentation if it does not include the IRIS data that contains the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the teaching hospital's cost report. This proposal would continue to require all teaching hospitals to submit the IRIS data under § 413.24(f)(5) to have an acceptable cost report submission. However, this proposal would require that this data must correspond to the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the teaching hospital's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. IRIS is the source document for reporting FTEs in all teaching hospitals' cost reports. To enhance the contractors' ability to review duplicates and to ensure residents are not being double-counted, we believe it is necessary and appropriate to require that the total unweighted and weighted FTE counts on the IRIS for direct GME and IME respectively, for all applicable allopathic, osteopathic, dental, and podiatric residents that a hospital may train, must equal the same total unweighted and weighted FTE counts for direct GME and IME reported on Worksheet E–4 and Worksheet E, Part A. Because all teaching hospitals are already required to submit the IRIS data under § 413.24(f)(5) to have an acceptable cost report submission, there are no additional burdens or expenses placed upon teaching hospitals as a result of our proposal to require that the supporting documents submitted (the IRIS data) correspond to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.3. of the preamble of this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a cost report is rejected for lack of supporting documentation if it does not include a Medicare bad debt listing that corresponds to the bad debt amounts claimed in the provider's Medicare cost report. This proposal would not require providers claiming Medicare bad debt reimbursement to collect additional data. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. The cost report worksheet that incorporated Form CMS–339 continues to require providers who claim Medicare bad debt reimbursement to submit a bad debt listing with the cost report in order to have an acceptable cost report submission. Because of the existing requirement, there are no additional burdens or expenses placed upon providers to ensure that the supporting documentation, the bad debt listing, corresponds to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.4. of the preamble of this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a disproportionate share hospital payment adjustment, a cost report is rejected for lack of supporting documentation if it does not include a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. The provider must furnish such information to the contractor as may be necessary to assure proper payment by the program. Currently, when the supporting documentation regarding Medicaid eligible days is not submitted by DSH eligible hospitals with their cost report, contractors must request it. Tentative program reimbursement payments are often issued to providers upon the submission of the cost report, and a subsequent submission of supporting documentation may reveal an overstatement of a hospital's Medicaid eligible days with a resulting overpayment to the provider.

Requiring a provider to submit, as a supporting document with its cost report, a listing of the provider's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the DSH eligible hospital's cost report would be consistent with the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which require providers to maintain data that substantiates their costs. This proposal to require providers to submit the supporting documentation with the cost report would also facilitate accurate provider payment and

the contractor's review and verification of the cost report.

This proposal would not require hospitals claiming a DSH payment adjustment to collect additional data. Hospitals claiming a DSH payment adjustment are already collecting the data in order to report the hospital's Medicaid eligible days in the hospital's cost report. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is no additional burden placed upon hospitals as a result of our proposal to require them to submit these supporting documents along with their cost report, and to ensure the supporting documentation corresponds to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.5. of the preamble of this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a cost report is rejected for lack of supporting documentation if it does not include a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the provider's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. The provider must furnish such information to the contractor as may be necessary to assure proper payment by the program. Contractors regularly request that hospitals claiming charity care and/or uninsured discounts submit documentation to support their charity care and/or uninsured discounts reported in their cost report. This proposal to require providers to submit this supporting documentation with the cost report would facilitate accurate payment to the provider and the contractor's review and verification of the cost report.

This proposal would not require DSH eligible hospitals reporting charity care and/or uninsured discounts to collect additional data but would require them to submit the supporting documentation with the cost report rather than at a later time. Because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is no additional burden placed upon DSH eligible hospitals as a result of our proposal to require them to submit these supporting documents along with their cost report and to ensure the supporting documentation corresponds to the amounts reported in the cost report in order to have an acceptable cost report submission.

In section IX.B.6. of the preamble of this proposed rule, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2018, for a provider reporting costs on its cost report that are allocated from a home office or chain organization, a cost report is rejected for lack of supporting documentation if it does not include a copy of the Home Office Cost Statement completed by the home office or chain organization that corresponds to the amounts allocated from the home office or chain organization to the provider's cost report. This proposal would not require providers reporting costs on their cost report that are allocated from a home office or chain organization to collect additional data. Instead, this proposal would codify our longstanding policy requiring costs allocated from a home office or chain organization to a provider be substantiated on the provider's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. With our proposal, we anticipate more providers will submit the Home Office Cost Statement to support the amounts reported in their cost reports, in order to have an acceptable cost report submission. Because the existing burden estimate for a provider's cost report already reflects the requirement that providers collect, maintain, and submit this data, there is no additional burden placed upon providers as a result of our proposal to require them to submit these supporting documents along with their cost report, in order to have an acceptable cost report submission.

14. Effect of Proposed Revisions Regarding Physician Certification and Recertification of Claims

In section XI. of the preamble of this proposed rule, we discuss our proposal to remove from the regulations the requirement that a physician statement of certification or recertification must itself indicate where that supporting information is to be found in the medical record. While moving this provision would have no substantive impact, we have examined the impact of eliminating the provision pertaining to where the supporting information is to be found and believe that substantial time and money would be saved by physicians when completing both certification and recertification statements. On average, we estimate that it requires approximately 9 minutes for the precise location of the various elements to be identified and recorded in the statements. This time currently is expended not only with the completion of an initial certification statement but each time a recertification statement is completed.

While the proposed elimination of this provision would benefit physicians in terms of reducing the amount of time expended in completing certification and recertification statements, it would also benefit physicians whose claims have been denied either because the physician failed to include this information in the certification and/or recertification statement or failed to accurately account for the information in the statements. In fact, these claims are routinely denied even in situations where the location of the information within a paper medical record is readily apparent to the reviewer. Given the improved capabilities of searchable electronic health records, these types of denials are increasingly unnecessary. We also expect a positive impact for beneficiaries because beneficiaries would no longer receive notices that these claims were denied, which inevitably caused confusion given the nature of these denials. Moreover, the denial of claims due to the failure to include the location of information within a paper medical record results in appeals. As an example, these denials are significant for skilled nursing facility (SNF) claims. In the SNF setting, a required element of the certification and recertification statement is the required estimated length of need (ELON) element. The table below shows in Row 1 the SNF improper payment rates for claims in error (certification statement does not indicate where in the medical record the required information of ELON is to be found; however the medical record contains the missing information); and in Row 2, the error rate if these claims are no longer considered to be erroneous (due to removal of the provision in the regulations). The data shown in the table are from the 2017 CERT reporting period and includes claims from July 1, 2015 through June 30, 2016.

Provider type	Label	Projected dollars in error	Projected dollars paid	Improper payment rate (%)	95 percent confidence interval
SNF	ELON Claims in Error	$3,259,219,132	$34,949,922,572	9.3	7.6–11.0
SNF	ELON Claims Not in Error	2,776,135,742	34,949,922,572	7.9	6.3–9.5

Overall, there is a 1.4 percentage point reduction in the improper payment rate in the SNF setting alone. The impact on the SNF setting is significant. Yet, if this 1.4 percentage point is considered uniformly across all provider settings, the magnitude of this provision and its impact on the Medicare Trust funds is extensive. Moreover, by eliminating these denials and subsequent appeals, MACS would have more time to dedicate to other more pertinent appeal issues.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2017 update of the FY 2017 MedPAR file and the December 2017 update of the Provider-Specific File (PSF) that is 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 2017 update of the most recently available hospital cost report data (FYs 2015 and 2016) 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 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 2017 update of the FY 2017 MedPAR file, we simulated payments under the capital IPPS for FY 2018 and proposed payments for FY 2019 for a comparison of total payments per case. Any 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 2019 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. We then 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:

- We estimate that the Medicare case-mix index would increase by 0.5 percent in both FYs 2018 and 2019.
- We estimate that Medicare discharges would be approximately 11.0 million in FY 2018 and 11.1 million in FY 2019.
- 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.a. of the Addendum to this proposed rule, the proposed update is 1.2 percent for FY 2019.
- In addition to the proposed FY 2019 update factor, the proposed FY 2019 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9997 and a proposed outlier adjustment factor of 0.9494.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of our proposed changes for FY 2019 on total capital payments per case, using a universe of 3,257 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2017 update of the FY 2017 MedPAR file, the December 2017 update to the PSF, and the most recent cost report data from the December 2017 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2018 and estimated proposed total payments per case for FY 2019 based on the proposed FY 2019 payment policies. Column 2 shows estimates of payments per case under our model for FY 2018. Column 3 shows estimates of proposed payments per case under our model for FY 2019. Column 4 shows the total percentage change in payments from FY 2018 to FY 2019. The change represented in Column 4 includes the proposed 1.2 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 2019 are expected to increase as compared to capital payments per case in FY 2018. This expected increase overall is largely due to the proposed 1.2 percent update to the capital Federal rate for FY 2019. Hospitals within both rural and urban regions may experience an increase or a decrease in capital payments per case due to proposed changes in the GAFs. These regional effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and 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 1.7 percent change in capital payments per case from FY 2018 to FY 2019 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in urban classifications would experience an increase in capital IPPS payments per case in FY 2019 as compared to FY 2018, while those hospitals in rural classifications would experience a decrease in capital IPPS payments. Capital IPPS payments per case would increase by an estimated 2.9 percent for hospitals in large urban areas and by 1.0 for hospitals in other urban areas, while payments to hospitals in rural areas would decrease by 1.4 percent, from FY 2018 to FY 2019.

The comparisons by region show that the estimated increases in capital payments per case from FY 2018 to FY 2019 in urban areas would range from a 0.3 percent increase for the Mountain urban region to a 3.7 percent increase for the Pacific urban region. For rural regions, the Mountain rural region is projected to experience the largest increase in capital IPPS payments per case of 0.9 percent, while the East South Central rural region is projected to experience a decrease in capital IPPS payments per case of 2.9 percent.

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 2018 to FY 2019. The proposed increase in capital payments for voluntary hospitals is estimated to be 1.5 percent. Government hospitals and proprietary hospitals are expected to experience an increase in capital IPPS payments of 2.9 and 1.8 percent, respectively.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2019. 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 2019, we show the average capital payments per case for reclassified hospitals for FY 2019. Urban reclassified hospitals are expected to experience an increase in capital payments of 0.7 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.7 percent. The estimated percentage decrease for rural reclassified hospitals is 2.3 percent, and for rural nonreclassified hospitals, the estimated percentage decrease in capital payments is 0.1 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2018 payments compared to proposed FY 2019 payments]

	Number of hospitals	Average FY 2018 payments/ case	Proposed average FY 2019 payments/ case	Change
By Geographic Location:				
All hospitals	3,257	948	964	1.7
Large urban areas (populations over 1 million)	1,310	1,021	1,051	2.9
Other urban areas (populations of 1 million of fewer)	1,170	938	947	1.0

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2018 payments compared to proposed FY 2019 payments]

	Number of hospitals	Average FY 2018 payments/ case	Proposed average FY 2019 payments/ case	Change
Urban hospitals	2,480	979	999	2.0
0–99 beds	638	795	818	2.9
100–199 beds	763	843	860	2.0
200–299 beds	438	903	918	1.7
300–499 beds	427	989	1,008	1.9
500 or more beds	214	1,175	1,200	2.1
Rural hospitals	777	669	660	−1.4
0–49 beds	299	548	559	2.0
50–99 beds	279	605	616	1.8
100–149 beds	116	680	655	−3.7
150–199 beds	44	731	705	−3.5
200 or more beds	39	815	786	−3.6
By Region:				
Urban by Region	2,480	979	999	2.0
New England	113	1,070	1,093	2.1
Middle Atlantic	310	1,074	1,091	1.6
South Atlantic	401	871	886	1.7
East North Central	385	942	953	1.1
East South Central	147	825	843	2.1
West North Central	158	963	980	1.8
West South Central	378	887	912	2.8
Mountain	163	1,021	1,024	0.3
Pacific	374	1,244	1,291	3.7
Puerto Rico	51	448	452	1.0
Rural by Region	777	669	660	−1.4
New England	20	927	919	−0.9
Middle Atlantic	53	643	637	−0.9
South Atlantic	122	622	609	−2.1
East North Central	114	679	672	−1.0
East South Central	150	623	605	−2.9
West North Central	94	710	704	−0.9
West South Central	147	594	588	−1.0
Mountain	54	741	748	0.9
Pacific	23	865	858	−0.8
By Payment Classification:				
All hospitals	3,257	948	964	1.7
Large urban areas (populations over 1 million)	1,325	1,020	1,050	2.9
Other urban areas (populations of 1 million of fewer)	956	903	924	2.3
Rural areas	976	869	852	−1.9
Teaching Status:				
Non-teaching	2,162	804	816	1.5
Fewer than 100 Residents	846	916	930	1.5
100 or more Residents	249	1,316	1,346	2.4
Urban DSH:				
Non-DSH	520	870	888	2.1
100 or more beds	1,483	993	1,020	2.7
Less than 100 beds	365	724	748	3.4
Rural DSH:				
Sole Community (SCH/EACH)	258	663	660	−0.5
Referral Center (RRC/EACH)	367	941	919	−2.4
Other Rural:				
100 or more beds	27	892	855	−4.2
Less than 100 beds	127	537	550	2.5
Urban teaching and DSH:				
Both teaching and DSH	818	1,064	1,095	2.9
Teaching and no DSH	88	917	933	1.7
No teaching and DSH	1,030	842	861	2.3
No teaching and no DSH	345	852	874	2.6
Rural Hospital Types:				
RRC/EACH	328	975	964	−1.1
SCH/EACH	311	750	752	0.2
SCH, RRC and EACH	133	807	792	−1.9
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2018 Reclassifications:.				
All Urban Reclassified	633	999	1,006	0.7
All Urban Non-Reclassified	1,795	972	998	2.7

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2018 payments compared to proposed FY 2019 payments]

	Number of hospitals	Average FY 2018 payments/ case	Proposed average FY 2019 payments/ case	Change
All Rural Reclassified	278	708	692	−2.3
All Rural Non-Reclassified	452	612	611	−0.1
All Section 401 Reclassified Hospitals	246	1,018	996	−2.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	654	660	0.9
Type of Ownership:				
Voluntary	1,901	963	978	1.5
Proprietary	854	856	872	1.8
Government	501	985	1,013	2.9
Medicare Utilization as a Percent of Inpatient Days:				
0–25	546	1,105	1,128	2.0
25–50	2,121	948	965	1.8
50–65	477	781	786	0.6
Over 65	73	547	558	2.2
Invalid/Missing Data	39	1,108	1,311	18.4

J. Effects of Proposed Payment Rate Changes and Proposed 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 proposed annual update to the payment rates for the LTCH PPS for FY 2019. In the preamble of this proposed rule, we specify the statutory authority for the provisions that are presented, identify the proposed policies, 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 proposed 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 409 LTCHs included in this impact analysis. We note that, although there are currently approximately 417 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the proposed FY 2019 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this proposed rule. Moreover, in the claims data used for this proposed rule, 1 of these 409 LTCHs only have claims for site neutral payment rate cases and are thus not included in our impact analysis for LTCH PPS standard Federal payment rate cases.) In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, the proposed 1.0115 percent annual update to the LTCH PPS standard Federal payment rate, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, the proposed elimination of the 25-pecent threshold policy and corresponding proposed one-time permanent budget neutrality adjustment (discussed in VII.E. of the preamble of this proposed rule), and the best available claims and CCR data to estimate the proposed change in payments for FY 2019.

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); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate HCO 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. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523.

Based on the best available data for the 409 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2019 would decrease by approximately 0.1 percent (or approximately $5 million) based on the proposed rates and factors presented in section VII. of the preamble and section V. of the Addendum to this proposed rule.

Based on the FY 2017 LTCH cases that were used for the analyses in this proposed rule, approximately 36 percent of those cases were classified as site neutral payment rate cases (that is, 36 percent of LTCH cases did not meet the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2018 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 2019, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 1.1 percent (or approximately $11 million).

Approximately 64 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2019, and would 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 2019 would increase approximately 0.2 percent (or approximately $6 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2019 is primarily due to the proposed 1.15 percent annual update to the LTCH PPS standard Federal payment rate for FY 2019 (discussed in section V.A. of the Addendum to this proposed rule) and the proposed −0.9 percent one-time permanent budget neutrality adjustment under our proposal to eliminate the 25-percent threshold policy.

Based on the 409 LTCHs that were represented in the FY 2017 LTCH cases that were used for the analyses in this proposed rule presented in this Appendix, we estimate that aggregate FY 2019 LTCH PPS payments would be approximately $4.510 billion, as compared to estimated aggregate FY 2018 LTCH PPS payments of approximately $4.515 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $5 million. We note that the estimated $5 million decrease in LTCH PPS payments in FY 2019 does not reflect changes in LTCH admissions or case-mix intensity, which would also affect the overall payment effects of the proposed policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2018 is $41,415.11. For FY 2019, we are proposing to establish an LTCH PPS

standard Federal payment rate of $41,482.98 which reflects the proposed 1.15 percent annual update to the LTCH PPS standard Federal payment rate, the proposed area wage budget neutrality factor of 0.999713 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate payments, and the proposed one-time permanent budget neutrality adjustment of 0.990535 to ensure that our proposed elimination of the 25-percent threshold policy (discussed in VII.E. of the preamble of this proposed rule) do not influence aggregate LTCH PPS payments. 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 to establish an LTCH PPS standard Federal payment rate of $40,662.75. This proposed LTCH PPS standard Federal payment rate reflects the proposed 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 proposed FY 2019 LTCH PPS standard Federal payment rate are applied to the FY 2018 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xiv) (that is, $41,415.11).

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 1.15 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.1 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019, on average, for all LTCHs (Column 6). In addition to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2019, the estimated increase of 1.1 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases that would be paid using methodologies that 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 of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the proposed LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the 1.15 percent annual update for FY 2019.

For FY 2019, we are proposing to update the wage index values based on the most recent available data, and we are proposing to continue to use labor market areas based on the OMB CBSA delineations (as discussed in section V.B. of the Addendum to this proposed rule). In addition, we are proposing to maintain the labor-related share at 66.2 percent under the LTCH PPS for FY 2019, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the 2013-based LTCH market basket. We also are proposing to apply a proposed area wage level budget neutrality factor of 0.999713 to ensure that the changes to the wage data and labor-related share do not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

As we discuss in VII.E. of the preamble of this proposed rule, we are proposing to eliminate the 25-percent threshold policy in a budget neutral manner. Therefore, for FY 2019, we are proposing to apply a one-time permanent budget neutrality factor of 0.990535 to ensure the proposed elimination of the 25-percent threshold policy does not result in any change in estimated aggregate LTCH PPS payments.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases would decrease from FY 2018 to FY 2019. Based on the FY 2017 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2018 HCO threshold of $27,381 (as established in the FY 2018 IPPS/LTCH PPS final rule) would result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2018 that are above the 7.975 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases would be approximately 7.988 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2018. Combined with our estimate that FY 2019 HCO payments for LTCH PPS standard Federal payment rate cases would be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2019, this would result in a negligible estimated decrease in HCO payments of less than 0.1 percent between FY 2018 and FY 2019. We note that, consistent with past practice, in calculating these estimated HCO payments, we increased estimated costs by our actuaries' projected market basket percentage increase factor.

Table IV shows the estimated impact of the proposed payment rate and proposed policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2019 by comparing estimated FY 2018 LTCH PPS payments to estimated FY 2019 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.4. 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 decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts would result in appropriate Medicare payments that are consistent with the statute.

2. 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 no change 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 2017 data for the 21 rural LTCHs (out of 409 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. 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, including any applicable HCO payments, or 100 percent of the estimated cost of the case. 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. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2019 of approximately $5 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $6 million and the projected decrease in payments to site neutral payment rate cases of approximately $11 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

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 2019

LTCH PPS payments (that is, FY 2017 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the proposed 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 proposed changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.4. of this Appendix refers only to the impact on proposed LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. 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 412.538. 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), 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 proposed 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 2019, it is necessary to estimate payments per discharge for FY 2018 using the rates, factors, and the policies established in the FY 2018 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2019 using the proposed rates, factors, and the policies in this FY 2019 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. Calculation of Proposed 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 proposed policies on proposed payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2018 and proposed FY 2019 payments on a case-by-case basis using historical LTCH claims from the FY 2017 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 2017 MedPAR files. For modeling FY 2018 LTCH PPS payments, we used the FY 2018 standard Federal payment rate of $41,415.11 (or $ 40,595.02 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 2019 LTCH PPS standard Federal payment rate, we used the proposed FY 2019 standard Federal payment rate of $41,482.98 (or $40,662.75 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 2018 LTCH PPS payments, we used the current FY 2018 labor-related share (66.2 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2018 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2018 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,381 (as discussed in section V.D. of the Addendum to that final rule), and the FY 2018 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2018 nonlabor-related share (33.8 percent) for LTCHs located in Alaska and Hawaii.

Similarly, for modeling proposed FY 2019 LTCH PPS payments, we used the proposed FY 2019 LTCH PPS labor-related share (66.2 percent), the proposed FY 2019 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 proposed FY 2019 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,639 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2019 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the FY 2019 nonlabor-related share (33.8 percent) for LTCHs located in Alaska and Hawaii.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2018 to FY 2019 based on the proposed payment rates and proposed 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 proposed 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 2018 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 2019 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 2018 to FY 2019 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 2018 to FY 2019 for proposed changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of the proposed area wage level budget neutrality factor (as discussed in section V.B. 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 2018 (Column 4) to FY 2019 (Column 5) for all proposed changes.

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND PROPOSED POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2019

[Estimated FY 2018 payments compared to estimated FY 2019 payments]

LTCH classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2018 LTCH PPS payment per standard payment rate	Average proposed FY 2019 LTCH PPS payment per standard payment rate [1]	Proposed percent change due to change to the proposed annual update to the standard federal rate [2]	Proposed percent change due to proposed changes to area wage adjustment with wage budget neutrality [3]	Proposed percent change due to all proposed standard payment rate changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
All Providers	409	74,978	$47,125	$47,205	1.1	0.0	0.2
By Location:							
Rural	21	2,494	39,412	39,405	1.1	−0.2	0.0
Urban	388	72,484	47,390	47,473	1.1	0.0	0.2
Large	196	40,272	50,584	50,738	1.1	0.0	0.3
Other	192	32,212	43,398	43,392	1.1	0.0	0.0
By Participation Date:							
Before Oct. 1983	11	1,910	43,040	42,764	1.1	−0.5	−0.6
Oct. 1983–Sept. 1993	42	9,584	52,189	52,476	1.1	0.2	0.5
Oct. 1993–Sept. 2002	169	31,176	45,745	45,783	1.1	0.0	0.1
After October 2002	187	32,308	47,195	47,276	1.1	0.0	0.2
By Ownership Type:							
Voluntary	77	10,529	49,341	49,513	1.1	0.2	0.3
Proprietary	319	62,700	46,608	46,670	1.1	0.0	0.1
Government	13	1,749	52,316	52,503	1.1	0.0	0.4
By Region:							
New England	12	2,684	43,020	42,791	1.1	−0.3	−0.5
Middle Atlantic	24	5,929	50,944	51,276	1.1	0.1	0.7
South Atlantic	66	13,670	48,296	48,379	1.1	−0.2	0.2
East North Central	68	11,782	46,537	46,446	1.1	−0.4	−0.2
East South Central	36	6,335	45,480	45,581	1.1	−0.1	0.2
West North Central	28	4,390	45,904	45,807	1.1	−0.2	−0.2
West South Central	120	18,278	41,768	41,750	1.1	0.1	0.0
Mountain	29	4,048	48,082	48,022	1.1	−0.3	−0.1
Pacific	26	7,862	58,460	59,090	1.2	0.8	1.1
By Bed Size:							
Beds: 0–24	43	5,094	47,085	47,049	1.1	−0.2	−0.1
Beds: 25–49	187	26,483	44,734	44,782	1.1	0.0	0.1
Beds: 50–74	105	19,580	48,176	48,274	1.1	0.0	0.2
Beds: 75–124	42	10,938	50,444	50,649	1.1	0.1	0.4
Beds: 125–199	23	7,944	47,519	47,442	1.1	−0.3	−0.2
Beds: 200+	9	4,939	47,834	48,112	1.1	0.5	0.6

[1] Estimated FY 2019 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed 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 2018 to FY 2019 for the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Proposed percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019 for proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Proposed percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 (shown in Column 4) to FY 2019 (shown in Column 5), including all of the proposed 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 proposed percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the proposed percent changes in estimated payments per discharge for the proposed annual update to the LTCH PPS standard Federal payment rate (Column 6) and 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.

d. Results

Based on the FY 2017 LTCH cases (from 409 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 proposed 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 0.2 percent, on average, for all LTCHs from FY 2018 to FY 2019 as a result of the proposed payment rate and proposed policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 0.2 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2019 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2018 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.4. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2019 by 1.15 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. Consistent with § 412.523(d)(4), we also are proposing to apply an area wage level budget neutrality factor to the proposed FY 2019 LTCH PPS standard Federal payment rate of 0.999713, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Finally, we are proposing to make a budget neutrality adjustment of 0.990535 for our proposed elimination of the 25-percent threshold

policy (discussed in VII.E. of the preamble of this proposed rule). 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 1.15 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.1 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2018 to FY 2019. This is because our estimate of the proposed changes in payments due to the proposed 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 less than 1.1 percent due to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2019.

(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 3 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 proposed overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019 for all hospitals is 0.2 percent. However, for rural LTCHs, estimated payments for LTCH PPS standard Federal payment rate cases are expected to remain constant. This is primarily driven by a projected decrease resulting from changes to the proposed changes to the area wage index adjustment. For urban LTCHs, we estimate an increase of 0.2 percent from FY 2018 to FY 2019. Among the urban LTCHs, large urban LTCHs are projected to experience an increase of 0.3 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019, and such payments for the remaining urban LTCHs are projected to remain constant from FY 2018 to FY 2019, as shown in Table IV.

(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 43 percent) are in LTCHs that began participating in the Medicare program after October 2002, and they are projected to experience a 0.2 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019, 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 decrease of 0.6 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993, and these LTCHs are projected to experience an increase of 0.5 percent in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019. LTCHs that began participating in the Medicare program between October 1993 and October 1, 2002, which treat approximately 41 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.1 percent increase in estimated payments from FY 2018 to FY 2019.

(3) Ownership Control

LTCHs are grouped into four categories based on ownership control type: Voluntary, proprietary, government and unknown. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 78 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience a 0.3 percent increase in payments to LTCH PPS standard Federal payment rate cases, while proprietary LTCHs are expected to experience an average increase of 0.1 percent in payments to LTCH PPS standard Federal payment rate cases. Government owned and operated LTCHs, meanwhile, are expected to experience a 0.4 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2018 to FY 2019.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2019 are projected to increase across 4 of the 9 census regions. LTCHs located in the East and West North Central regions and the Mountain region are projected to experience a slight decrease of 0.1 and 0.2 percent, respectively, while LTCHs located New England are expected to experience a 0.5 decrease in payments. All other regions are projected to experience constant or increased payments per discharge for FY 2019 in comparison to FY 2018. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases will have the largest positive impact on LTCHs in the Pacific region (1.1 percent) and the Middle Atlantic region (0.7 percent) as shown in Table IV. These regional variations are largely due to proposed updates in the wage index.

(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 would experience a decrease in payments for LTCH PPS standard Federal payment rate cases of 0.1 percent, while LTCHs with 125–199 beds are expected to experience a decrease of 0.2 percent. We expect the remaining categories to experience an increase in payments of 0.1 and 0.2 percent for LTCHs with 25–49 and 50–74 beds, respectively, a 0.4 percent increase in payments for LTCHs with 75–124 beds, and a 0.6 increase for LTCHs with 200 or more beds.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2019 relative to FY 2018 of approximately 6 million (or approximately 0.2 percent) for the 409 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 would result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2019 relative to FY 2018 of approximately $11 million (or approximately 1.1 percent) for the 409 LTCHs in our database. Therefore, we project that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to all LTCH cases in FY 2019 relative to FY 2018 of approximately $5 million (or approximately 0.1 percent) for the 409 LTCHs in our database.

5. 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 above, we do not expect the continued implementation of the site neutral payment system to have a negative impact 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

1. Background

In section VIII.A. of the preamble of this proposed rule, we discuss our current and 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 2021 payment determination.

In this proposed rule, we are proposing to: (1) Extend eCQM reporting requirements to the CY 2019 reporting period/FY 2021 payment determination; (2) require the 2015 Edition of CEHRT for eCQMs beginning with the CY 2019 reporting period/FY 2021 payment determination; (3) remove 17 claims-based measures beginning with the CY 2018 reporting period/FY 2020 payment determination; (4) remove two structural

measures beginning with the CY 2018 reporting period/FY 2020 payment determination; (5) remove two claims-based measures beginning with the CY 2019 reporting period/FY 2021 payment determination; (6) remove eight chart-abstracted measures beginning with the CY 2019 reporting period/FY 2021 payment determination; (7) remove one claims-based measure beginning with the CY 2020 reporting period/FY 2022 payment determination; (8) remove one chart-abstracted measure beginning with the CY 2020 reporting period/FY 2022 payment determination; (9) remove seven eCQMs beginning with CY 2020 reporting period/FY 2022 payment determination; (10) remove one claims-based measure beginning with the CY 2021 reporting period/FY 2023 payment determination; and (11) adopt a new measure removal factor.

We do not believe our proposal to adopt a new measure removal factor will directly affect burden. However, as further explained in section XIV.B.3. of the preamble of this proposed rule, we believe that there will be an overall decrease in the estimated information collection burden for hospitals due to the other proposed policies. We refer readers to section XIV.B.3. of the preamble of this proposed rule for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail below.

2. Impact of Proposed Extension of eCQM Reporting Requirements

In the FY 2018 IPPS/LTCH PPS final rule, we finalized policies to require hospitals to submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38355 through 38361). In section VIII.A.11.d.(2) of the preamble of this proposed rule, we are proposing to extend those reporting requirements for the CY 2019 reporting period/FY 2021 payment determination, such that hospitals would be required to submit one, self-selected calendar quarter of data for four eCQMs in the Hospital IQR Program measure set. Therefore, we believe our burden estimate of 40 minutes per hospital per year (10 minutes per record $\times 4$ eCQMs $\times 1$ quarter) associated with eCQM reporting requirements finalized for the CY 2018 reporting period/FY 2020 payment determination will also apply to the CY 2019 reporting period/FY 2021 payment determination.

3. Impact of Proposed Requirement To Certify EHR to the 2015 Edition

In section VIII.A.11.d.(3) of the preamble of this proposed rule, we discuss our proposal to require use of EHR technology certified to the 2015 Edition beginning with the CY 2019 reporting period/FY 2021 payment determination, which aligns with previously established requirements in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). As described in section XIV.B.3.g. of the preamble of this proposed rule, we expect this proposal to have no impact on information collection burden for the Hospital IQR Program because this proposal does not require hospitals to submit new data to CMS.

With respect to any costs unrelated to data submission, although this proposal would require some investment in systems updates, the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition of CEHRT beginning with the CY 2019 reporting period/FY 2021 payment determination (80 FR 62761 through 62955). Because all hospitals participating in the Hospital IQR Program are subsection (d) hospitals that also participate in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of this proposal.

4. Impact of Proposed Removal of Chart-Abstracted Measures

In sections VIII.A.5.b.(2)(b) and VIII.A.5.b.(8) of the preamble of this proposed rule, beginning with the CY 2019 reporting period/FY 2021 payment determination, we are proposing to remove eight chart-abstracted measures—five National Health and Safety Network (NHSN) hospital-acquired infection (HAI) measures (CDI (NQF #1717), CAUTI (NQF #0138), CLABSI (NQF #0139), MRSA Bacteremia (NQF #1716), Colon and Abdominal Hysterectomy SSI (NQF #0753)) and three clinical process of care measures (ED–1 (NQF #0495), IMM–2 (NQF #1659), VTE–6 [405]). In section VIII.A.5.b.(8)(b) of the preamble of this proposed rule, beginning with the CY 2020 reporting period/FY 2022 payment determination, we also are proposing to remove one chart-abstracted clinical process of care measure (ED–2).

As described in detail in section XIV.B.3. of the preamble of this proposed rule, we expect our proposals to remove the clinical process of care chart-abstracted measures would reduce the information collection burden by 1,046,071 hours and approximately $38.3 million for the CY 2019 reporting period/FY 2021 payment determination, and an additional 901,200 hours and approximately $33 million for the CY 2020 reporting period/FY 2022 payment determination for the Hospital IQR Program. We note that the burden of data collection for the NHSN HAI measures (CDI, CAUTI, CLABSI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) is accounted for under the Centers for Disease Control and Prevention (CDC) National Health and Safety Network (NHSN) OMB control number 0920–0666. Because burden associated with submitting data for the NHSN HAI measures is captured under a separate OMB control number, we do not provide an independent estimate of the information collection burden associated with these measures for the Hospital IQR Program.

The data validation activities, however, are conducted by CMS. Since the measures were adopted into the Hospital IQR Program, CMS has validated the data for purposes of the Program. Therefore, this burden has been captured under the Hospital IQR Program's OMB control number 0938–1022. While we did not propose any changes directly to the validation process related to chart-abstracted measures, if our proposals to remove five NHSN HAI and four clinical process of care chart-abstracted measures (in section VIII.A.5.b.(2)(b) and section VIII.A.5.b.(8) of the preamble of this proposed rule) are finalized as proposed, we believe that hospitals will experience an overall reduction in burden associated with validation of chart-abstracted measures beginning with the FY 2022 payment determination because hospitals selected for validation are currently required to submit validation templates for the NHSN HAI measures for the Hospital IQR Program. In addition, if our proposals to remove the NHSN HAI measures are finalized, the information collection burden associated with submission of these validation templates would be eliminated from the Hospital IQR Program. As described in detail in section XIV.B.3. of the preamble of this proposed rule, we estimate a total decrease of 43,200 hours and approximately $1.6 million as a result of discontinuing submission of NHSN HAI validation templates under the Hospital IQR Program as described in section IV.K.4.e. of the preamble of this proposed rule. The proposed removal of NHSN HAI measures from the Hospital IQR Program, the subsequent cessation of validation processes for the NHSN HAI measures, the retention of these measures in the HAC Reduction Program, and the proposed implementation of a validation process for these measures under the HAC Reduction Program, represent no net change in information collection burden for the NHSN HAI measures across CMS hospital quality programs. Therefore, we do not anticipate any change under the CDC NHSN's OMB control number 0920–0666 due to our proposals.

Furthermore, we anticipate that the costs to hospitals participating in the Hospital IQR Program, beyond that associated with information collection, will be reduced because hospitals would no longer need to review multiple feedback reports for the NHSN HAI measures from three different hospital quality programs (the Hospital IQR, Hospital VBP, and HAC Reduction Programs) that use three different reporting periods, which result in interpreting slightly different measure rates for the same measures (under the Hospital IQR Program, a rolling four quarters of data are used to update the *Hospital Compare* website; under the Hospital VBP Program, 1-year periods are used for each of the baseline period and the performance period; and under the HAC Reduction Program, a 2-year performance period is used).

5. Impact of Proposed Removal of Two Structural Measures

In section VIII.A.5.a. and VII.A.5.b.(1) of the preamble of this proposed rule, we are proposing to remove two structural measures, Hospital Survey on Patient Safety Culture and Safe Surgery Checklist, beginning with the CY 2018 reporting period/FY 2020 payment determination. We believe these

[405] NQF endorsement has been removed.

proposals will result in a minimal information collection burden reduction, which is addressed in section XIV.B.3. of the preamble of this proposed rule. In addition, we refer readers to VIII.A.4.b. of the preamble of this proposed rule, where we acknowledge that costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Program requirements. We believe it may be unnecessarily costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). As discussed in sections VIII.A.5.a. and VIII.A.5.b.(1) of the preamble of this proposed rule, we believe these measure are of limited utility for internal hospital quality improvement efforts because they do not provide individual patient level data or any information on patient outcomes. In addition, our analyses show that use of patient safety culture surveys and safe surgery checklists is widely in practice among hospitals. Therefore, we do not believe that these measures support the program objectives of facilitating internal hospital quality improvement efforts or informing beneficiary choice.

6. Impact of the Proposed Removal of Claims-Based Measures

In sections VIII.A.5.b.(2)(a), (3), (4), (6), and (7) of the preamble of this proposed rule, we are proposing to remove 17 claims-based measures PSI–90 (NQF #0531), READM–30–AMI (NQF #0505), READM–30–CABG (NQF #2515), READM–30–COPD (NQF #1891), READM–30–HF (NQF #0330), READM–30–PN (NQF #0506), READM–30–THA/TKA (NQF #1551), READM–30–STK, MORT–30–AMI (NQF #0230), MORT–30–HF (NQF #0229), MSPB (NQF #2158), Cellulitis Payment, GI Payment, Kidney/UTI Payment, AA Payment, Chole and CDE Payment, and SFusion Payment) beginning with the CY 2018 reporting period/CY 2020 payment determination. In addition, in section VIII.A.5.b.(4) of the preamble of this proposed rule, we are proposing to remove two claims-based measures (MORT–30–COPD (NQF #1893) and MORT–30–PN (NQF #0468)) beginning with the CY 2019 reporting period/FY 2021 payment determination. Furthermore, in sections VIII.A.5.b.(4) and VIII.A.5.b.(5), respectively, of the preamble of this proposed rule, we are proposing to remove one-claims based measure (MORT–30–CABG (NQF #2558)) beginning with the CY 2020 reporting period/FY 2022 payment determination and one claims-based measure (Hip/Knee Complications (NQF #1550)) beginning with the CY 2021 reporting period/FY 2023 payment determination.

These claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, therefore, we do not believe removing these measures will impact the information collection burden on hospitals. Nonetheless, we anticipate that hospitals will experience a general cost reduction associated with these proposals stemming from no longer having to review and track various program requirements or measure information in multiple confidential feedback and preview reports from multiple programs that reflect multiple measure rates due to varying scoring methodologies and reporting periods.

7. Impact of the Proposed Removal of eCQMs

In section VIII.A.5.b.(9) of the preamble of this proposed rule, we are proposing to remove seven eCQMs from the Hospital IQR Program eCQM measure set beginning with the CY 2020 reporting period/FY 2022 payment determination. As described in section XIV.B.3. of this proposed rule, we do not anticipate that removal of these seven eCQMs will affect the information collection burden for hospitals. However, as discussed in section VIII.A.4.b. of the preamble of this proposed rule, we believe costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Program requirements, such as maintaining measure specifications in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program. We further discuss costs unrelated to information collection associated with eCQM removal in section VIII.A.5.b.(9) of the preamble of this proposed rule.

8. Summary of Effects

In summary, we estimate: (1) A total information collection burden reduction of 1,046,138 hours (−1,046,071 hours due to the proposed removal of ED–1 (NQF #0495), IMM–2 (NQF #1659), and VTE–6 [406] measures for the CY 2019 reporting period/FY 2021 payment determination and −67 hours for no longer collecting data for the voluntary Hybrid HWR measure [407]) and a total cost reduction related to information collection of approximately $38.3 million (−1,046,138 hours × $36.58 per hour [408]) for the CY 2019 reporting period/FY 2021 payment determination; and (2) a total information collection burden reduction of 901,200 hours (−858,000 hours due to the proposed removal of ED–2 −43,200 hours due to the proposed discontinuation of the NHSN HAI measure validation process under the Hospital IQR Program) and a total cost reduction related to information collection of approximately $33 million (−901,200 hours × $36.58 per hour [409]) for the CY 2020 reporting period/FY 2022 payment determination. As stated earlier, we also anticipate additional cost reductions unrelated to the information collection burden associated with our proposals, including, for example, no longer having to review and track measure information in multiple feedback reports from multiple programs and maintaining measure specifications in hospitals' EHR systems for all eCQMs available for use in the program.

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 or slightly decrease. We believe that reducing the number of chart-abstracted measures used in the Hospital IQR Program would, at least in part, help increase hospitals' chances to meet all Program requirements and receive their full annual percentage increase.

We refer readers to section XIV.B.3. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the burden of the requirements for submitting data to the Hospital IQR Program.

L. Effects of Proposed 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.3.b. of the preamble of this proposed rule, we are proposing to remove four web-based, structural measures: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389), and two chart-abstracted, NHSN measures: (5) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and (6) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) beginning with the FY 2021 program year. In addition, in section VIII.B.4. of the preamble of this proposed rule, we are proposing to adopt one claims-based measure for the FY 2021 program year and subsequent years: 30-Day Unplanned Readmissions for Cancer Patients measure (NQF #3188). If

[406] NQF Endorsement has been removed.

[407] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized our proposal to collect data on a voluntary basis for the Hybrid HWR measure for the CY 2018 reporting period/FY 2020 payment determination. We estimated that approximately 100 hospitals would voluntarily report data for this measure, resulting in a total burden of 67 hours across all hospitals for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38504). Because we only finalized voluntary collection of data for one year, voluntary collection of this data would no longer occur beginning with the CY 2019 reporting period/FY 2021 payment determination and subsequent years resulting in a reduction in burden of 67 hours across all hospitals.

[408] In the FY 2017 IPPS/LTCH PPS final rule (82 FR 38501), we finalized an hourly wage estimate of $18.29 per hour, plus 100 percent overhead and fringe benefits, for the Hospital IQR Program. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $36.58 per hour.

[409] Ibid.

finalized, the PCHQR Program measure set would consist of 13 measures for the FY 2021 program. Further, in section XIV.B.4.b. of the preamble of this proposed rule, we are proposing to adopt a new time burden estimate, to be applied to structural and web-based tool measures for the FY 2021 program year and subsequent years. Specifically, we are proposing to adopt the estimate of 15 minutes for reporting these types of measures, which is the time estimate utilized by the Hospital IQR Program (80 FR 49762).

As explained in section XIV.B.4.c. of the preamble of this proposed rule, we anticipate that these proposed new requirements would reduce the overall burden on participating PCHs. If our proposal to apply 15 minutes per measure as a burden estimate for structural measures and web-based tool measures and our proposal to remove the following web-based structural measures: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH–14/NQF #0382); (2) Oncology: Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH–17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH–18/NQF #0389)) are finalized as proposed, we estimate a reduction of 1 hour (or 60 minutes) per PCH (15 minutes per measure × 4 measures = 60 minutes), and a total annual reduction of approximately 11 hours for all 11 PCHs (60 minutes × 11 PCHs/60 minutes per hour), as a result of the proposed removal of these four measures.

We further anticipate that the proposed removal of the two NHSN measures: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and (2) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) will result in a net burden decrease. If our proposal to remove the CAUTI and CLABSI measures is finalized as proposed, we estimate an annual burden reduction of 2,518 hours per PCH (1,259 hours × 2 measures = 2,518 hours) and an annual burden reduction of 27,698 hours across all 11 PCHs (2,518 hours × 11 PCHs = 27,698 hours).

We do not anticipate any increase in burden on the PCHs associated with our proposal to adopt a claims-based measure into the PCHQR Program beginning with the FY 2021 program year. This measure is claims-based and does not require facilities to report any additional data beyond that already submitted on Medicare administrative claims for payment purposes. Therefore, we do not believe that there is any associated burden with this proposal.

In summary, if our proposals to remove 6 measures are finalized as proposed, we estimate a total burden reduction of 27,709 hours of burden per year for all 11 PCHs (27,698 hours for the removal of the CAUTI & CLABSI measures + 11 hours for the removal of the 4 web-based, structural measures = 27,709 total hours), beginning with the FY 2021 program year.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Under the LTCH QRP, the Secretary reduces 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. Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual update for the FY 2019 payment determination.

We believe that the burden and costs associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. We intend to closely monitor the effects of this quality reporting program on LTCHs and to help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and help desks.

We refer readers to section XIV.B.6. of the preamble of this proposed rule for details discussing information collection requirements for the LTCH QRP.

N. Effects of Proposed Requirements Regarding the Promoting Interoperability Programs

In section VIII.D. of the preamble of this proposed rule, we are proposing a new performance-based scoring methodology and changes to the Stage 3 objectives and measures for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program. We also are proposing changes to the EHR reporting period in CYs 2019 and 2020; the CQM reporting period and criteria for CY 2019; and to codify the policies for subsection (d) Puerto Rico hospitals to participate in the Medicare Promoting Interoperability Program for eligible hospitals, including policies previously implemented through program instruction. We believe that, overall, these proposals would reduce burden. We refer readers to section XIV.B.9. of the preamble of this proposed rule for additional discussion on the information collection effects associated with these proposals.

In section VIII.D.12.a. of the preamble of this proposed rule, we are proposing to amend 42 CFR 495.324(b)(2) and 495.324(b)(3) to align with current prior approval policy for MMIS and ADP systems at 45 CFR 95.611(a)(2)(ii), and (b)(2)(iii) and (iv), and to minimize burden on States. Specifically, we are proposing that the prior approval dollar threshold in § 495.324(b)(3) would be increased to $500,000, and that a prior approval threshold of $500,000 would be added to § 495.324(b)(2). In addition, in light of these proposed changes, we are proposing a conforming amendment to amend the threshold in § 495.324(d) for prior approval of justifications for sole source acquisitions to be the same $500,000 threshold. That threshold is currently aligned with the $100,000 threshold in current 495.324(b)(3). Amending § 495.324(d) to preserve alignment with § 495.324(b)(3) maintain the consistency of our prior approval requirements. We believe that these proposals also would reduce burden on States by raising the prior approval thresholds and generally aligning them with the thresholds for prior approval of MMIS and ADP acquisitions costs.

In section VIII.D.12.b. of the preamble of this proposed rule, we are proposing to amend 42 CFR 495.322 to provide that the 90 percent FFP for Medicaid Promoting Interoperability Program administration would no longer be available for most State expenditures incurred after September 30, 2022. We are proposing a later sunset date, September 30, 2023, for the availability of 90 percent enhanced match for State administrative costs related to Medicaid Promoting Interoperability Program audit and appeals activities, as well as costs related to administering incentive payment disbursements and recoupments that might result from those activities. States would not be able to claim any Medicaid Promoting Interoperability Program administrative match for expenditures incurred after September 30, 2023. We do not believe that these proposals would impose any additional burdens on States. We refer readers to section XIV.B.9. of the preamble of this proposed rule for additional discussion on the information collection effects associated with these proposals.

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.

For example, as discussed in section II.F.2.d. of the preamble of this proposed rule, section II.H.5.a. of the preamble of this proposed rule, and section II.A.4.g. of the Addendum to this proposed rule, we believe that, in the context of the pending new technology add-on payment applications for two CAR T-cell therapy drugs, there may be merit in the suggestions from the public to create a new MS–DRG for the assignment of procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients who receive treatment involving CAR T-cell therapy as an alternative to our proposed MS–DRG assignment to MS–DRG 016 for FY 2019, or the suggestions to allow hospitals to utilize an alternative CCR specific to procedures involving CAR T-cell therapy drugs for purposes of outlier payments, new technology add-on payments, if approved, and payments to IPPS excluded cancer hospitals. We are considering these alternatives for FY 2019 and are seeking public comment on them.

We also are inviting comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices, which is a high priority for this Administration. In addition, we are considering alternative approaches and authorities to encourage value-based care and lower drug prices. We solicit comments on how the payment methodology alternatives may intersect and affect future participation in any such alternative approaches.

As discussed in section II.A.4.g. of the Addendum to this proposed rule, the impact

of an alternative CCR specific to procedures involving CAR T-cell therapy drugs is dependent on the relationship between the CCR that would otherwise be used and the alternative CCR used. For illustrative purposes, we discussed an example where if a hospital charged $400,000 for a procedure involving the utilization of the CAR T-cell therapy drug described by ICD–10–PCS code XW033C3, the application of a hypothetical CCR of 0.25 results in a cost of $100,000 (=$400,000 * 0.25), while the application of a hypothetical CCR of 1.00 results in a cost of $400,000 (=$400,000 * 1.0).

The impact of the creation of a separate MS–DRG for procedures involving the utilization of CAR T-cell therapy drugs and cases representing patients receiving treatment involving CAR T-cell therapy would be dependent on the relative weighting factor determined for the separate MS–DRG. We are inviting public comments on the most appropriate approach for determining the relative weighting factor under this alternative, such as an approach based on taking into account an appropriate portion of the average sales price (ASP) for these drugs, or other approaches. We note that our proposed relative weighting factor for MS–DRG 016 for FY 2019 can be found in Table 5 associated with this proposed rule (which is available via the internet on the CMS website).

As discussed in section VIII.A.5.b.(9) of the preamble of this proposed rule, in the context of removing seven eCQMs from the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years, we considered proposing to remove these seven eCQMs 1 year earlier, beginning with the CY 2019 reporting period/FY 2021 payment determination. Our analyses indicated no estimated change in average reporting burden between these two options. We interpret the lack of difference is due to very few hospitals choosing the seven eCQMs proposed for removal. Because the alternatives considered do not impact the collection of information for hospitals, we do not expect these alternatives to affect the reporting burden on hospitals associated with the Hospital IQR Program. We considered these alternatives and are seeking public comment on them.

As discussed in section IV.I.4.b. of the preamble of this proposed rule, in the context of scoring hospitals for purposes of the Hospital VBP Program for the FY 2021 program year and subsequent years, we analyzed two domain weighting options based on our proposals to remove 10 measures and the Safety domain from the Hospital VBP Program. As an alternative to our proposal to weight the three remaining domains as Clinical Outcomes domain (proposed name change)—50 percent; Person and Community Engagement domain—25 percent; and Efficiency and Cost Reduction domain—25 percent, we considered weighting each of the three remaining domains equally, meaning each of the three domains would be weighted as one-third of a hospital's Total Performance Score (TPS), beginning with the FY 2021 program year. As discussed in section IV.I.4.b. of the preamble of this proposed rule, we also considered keeping the current domain weighting (25 percent for each of the four domains—Safety, Clinical Outcomes (proposed name change), Person and Community Engagement, and Efficiency and Cost Reduction—with proportionate reweighting if a hospital has sufficient data on only three domains), which would require keeping at least one or more of the measures in the Safety domain and the Safety domain itself. As summarized in section IV.I.4.b.(3) of the preamble of this proposed rule, to understand the potential impacts of the proposed domain weighting on hospitals' TPSs, we conducted analyses using FY 2018 program data that estimated the potential impacts of our proposed domain weighting policy to increase the weight of the Clinical Outcomes domain from 25 percent to 50 percent of a hospital's TPS and an alternative weighting policy we considered of equal weights whereby each domain would constitute one-third (1/3) of a hospital's TPS. The table below provides an overview of the estimated impact on hospitals' TPS by certain hospital characteristics and as they would compare to actual FY 2018 TPSs, which include scoring on four domains, including the Safety domain, and applying proportionate reweighting if a hospital has sufficient data on only three domains.

COMPARISON OF ESTIMATED AVERAGE TPSS AND UNWEIGHTED DOMAIN SCORES *

Hospital characteristic	Actual FY 2018 average clinical care domain score	Actual FY 2018 average person and community engagement domain score	Actual FY 2018 average efficiency and cost reduction domain score	Actual FY 2018 average TPS (4 domains) +	Proposed increased weighting of clinical care domain: estimated average TPS	Alternative weighting: estimated average TPS
All Hospitals **	43.2	33.5	18.8	37.4	34.6	31.8
Bed Size:						
1–99	33.4	46.0	35.7	44.6	37.2	38.4
100–199	42.2	34.5	21.0	39.2	35.0	32.6
200–299	44.5	27.9	12.9	34.4	32.4	28.4
300–399	48.2	27.3	10.0	33.3	33.4	28.5
400+	50.9	26.9	7.6	31.9	34.1	28.5
Geographic Location:						
Urban	46.8	30.7	13.7	35.7	34.5	30.4
Rural	33.7	40.5	31.7	41.9	34.9	35.3
Safety Net Status ***:						
Non-Safety Net	42.7	35.4	19.0	37.9	34.9	32.4
Safety Net	45.1	25.7	18.1	35.6	33.5	29.6
Teaching Status:						
Non-Teaching	39.9	36.7	22.9	39.4	34.9	33.2
Teaching	48.7	27.9	11.8	34.1	34.3	29.5

* Analysis based on FY 2018 Hospital VBP Program data.

** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.

*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of Disproportionate Share Hospital (DSH) patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*.

The table below provides a summary of the estimated impacts on average TPSs and payment adjustments for all hospitals,[410] including as they would compare to actual FY 2018 program results under current domain weighting policies.

Summary of estimated impacts on average TPS and payment adjustments using FY 2018 program data	Actual (4 domains) +	Proposed increased weight for clinical outcomes (3 domains)	Equal weighting alternative (3 domains)
Total number of hospitals with a payment adjustment	2,808	2,701	2,701.
Number of hospitals receiving a positive payment adjustment (percent)	1,597 (57 percent)	1,209 (45 percent)	1,337 (50 percent).
Average positive payment adjustment percentage	0.60 percent	0.58 percent	0.70 percent.
Estimated average positive payment adjustment	$128,161	$233,620	$204,038.
Number of hospitals receiving a negative payment adjustment (percent)	1,211 (43 percent)	1,492 (55 percent)	1,364 (50 percent).
Average negative payment adjustment percentage	−0.41 percent	−0.60 percent	−0.57 percent.
Estimated average negative payment adjustment	$169,011	$189,307	$200,000.
Number of hospitals receiving a positive payment adjustment with a composite quality score * below the median (percent).	341 (21 percent)	134 (11 percent)	266 (20 percent).
Average TPS	37.4	34.6	31.8.
Lowest TPS receiving a positive payment adjustment	34.6	35.9	30.9.
Slope of the linear exchange function	2.8908851882	2.7849297316	3.2405954322.

+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.
* ''Composite quality score'' is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score.

We also refer readers to section I.H.6.b. of Appendix A of this proposed rule for a detailed discussion regarding the estimated impacts of the proposed domain weighting and equal weighting alternative on hospital percentage payment adjustments. Because the alternatives considered do not impact the collection of information for hospitals, we do not expect these alternatives to affect the reporting burden on hospitals. We considered these alternatives and are seeking public comment on them.

As discussed in section IV.J.5. of the preamble of this proposed rule, in the context of scoring hospitals for the purposes of the HAC Reduction Program, we analyzed two alternative scoring options to the current methodology for the FY 2020 program year and subsequent years. The alternative scoring methodologies considered are an Equal Measure Weights methodology, which would remove the domains and assign equal weight to each measure for which a hospital has a score, and a Variable Domain Weighting methodology, which would vary the weighting of Domain 1 and 2 based on the number of measures in each domain. We are considering these alternative approaches to allow the HAC Reduction Program to continue to fairly assess all hospitals' performance under the Program.

We simulated results under each scoring approach using FY 2018 HAC Reduction Program data. We compared the percentage of hospitals in the worst-performing quartile in FY 2018 to the percentage that would be in the worst-performing quartile under each scoring approach. The table below provides a high-level overview of the estimated impact of these approaches on several key groups of hospitals.

Hospital group [a]	Equal measure weights (percent)	Variable domain weights (percent)
Teaching hospitals: 100 or more residents (N=248)	2.4	1.6
Safety-net [b] (N=644)	0.6	0.8
Urban hospitals: 400 or more beds (N=360)	2.2	1.1
Hospitals with 100 or fewer beds (N=1,169)	−1.8	−0.9
Hospitals with a measure score for:		
Zero Domain 2 measures (N=188)	0.0	0.0
One Domain 2 measure (N=269)	−4.2	−1.9
Two Domain 2 measures (N=225)	−0.8	−0.4
Three Domain 2 measures (N=198)	−2.5	−2.5
Four Domain 2 measures (N=253)	−0.4	0.4
Five Domain 2 measures (N=2,022)	1.0	0.5

[a] The number of hospitals in the given hospital group for FY 2018 is specified in parenthesis in this column (for example, N=248).
[b] Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent.

As shown in the table above, the Equal Measure Weights approach generally has a larger impact than the Variable Domain Weights approach. Under the Equal Measure Weights Approach, as compared to the current methodology using FY2018 HAC Reduction Program data, the percentage of hospitals in the worst-performing quartile decreases by 1.8 percent for small hospitals (that is, 100 or fewer beds), 4.2 percent for hospitals with one Domain 2 measure, 0.8 percent for hospitals with two Domain 2 measures, while it increases by 2.2 percent for large urban hospitals (that is, 400 or more beds) and 2.4 percent for large teaching hospitals (that is, 100 or more residents). The Variable Domain Weights approach changes the percentage of hospitals in the worst-performing quartile by less than two percent for these groups of hospitals.

To understand the potential impacts of these alternatives on hospitals' Total HAC Reduction Program Penalty Amount, we conducted an analysis that estimated the potential impacts of these alternatives using FY 2013 payment data annualized by a factor to estimate in FY 2019 payment dollars. Based on this analysis, we expect that aggregate penalty amounts would slightly increase under both alternative methodologies proposed in this rule. We also expect an increase in the penalty amount under both methodologies because some larger hospitals may move into the worst-performing quartile and smaller hospitals may move out of the worst-performing quartile. Because the 1 percent penalty applies uniformly to hospitals in the worst-performing quartile, we anticipate that overall program penalties would rise slightly if more larger hospitals move into the penalty quartile. The alternative weighting approach considered, variable weighting, would increase estimated total penalties by approximately $7,585,812. The proposed

[410] Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed from this analysis.

weighting approach would increase estimated total penalties by $19,061,086, over $11 million more than the alternative weighting approach considered. The table below displays the results of our analysis in FY 2013 dollars, FY 2019 dollars, and as a percentage difference.

Scenario	Total HAC reduction program penalty amount (FY 2019 dollars) *	Percentage difference from FY 2018	Difference from FY 2018 (FY 2019 dollars) *
FY 2018 HAC Reduction Program—Before Proposed Weighting Change	$441,684,337	N/A	N/A
Variable Domain Weights	449,270,149	1.7	$7,585,812
Equal Measure Weights	460,745,424	4.3	19,061,086

* Estimated change in total penalties applied using FY 2013 payments annualized to FY 2019 payment dollars.

After consideration of the current policy, Equal Measure Weights and Variable Domain Weighting methodologies, we are seeking public comment on these approaches. Because the alternatives considered do not impact the collection of information for hospitals, we do not expect these alternatives to affect the reporting burden on hospitals associated with the HAC Reduction Program.

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, if finalized, is considered an E.O. 13771 deregulatory action. We estimate that this rule generates $72 million in annualized cost savings, discounted at 7 percent relative to fiscal year 2016, over a perpetual time horizon. We discuss the estimated burden and cost reductions for the Hospital IQR Program in section XIV.B.3. of the preamble of the proposed rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $21,585 per hospital annually or approximately $71,233,624 for all hospitals annually. We note that in section VIII.A.5.c.(1). of the preamble of this proposed rule, we are proposing to remove the hospital-acquired infection (HAI) measures from the Hospital IQR Program and, therefore, discontinue validation of these measures under the Hospital IQR Program. However, these measures will remain in the HAC Reduction Program and, therefore, we are proposing to begin validation of these measures under the HAC Reduction Program using the same processes and information collection requirements previously used under the Hospital IQR Program. As a result, the net costs reflected in the table below for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs. We discuss the estimated burden and cost impacts for the proposed transition of HAI data validation from the Hospital IQR Program to the HAC Reduction Program in section XIV.B.7. of the preamble of the proposed rule. We discuss the estimated burden and cost reductions for the PCHQR Program in section XIV.B.4. of the preamble of this proposed rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $92,145 per PCH annually or approximately $1,013,595 for all participating PCHs annually. We discuss the estimated burden and cost reductions for the proposed LTCH QRP measure removals in section XIV.B.6. of the preamble of this proposed rule, and estimate that the impact of these proposed changes is a reduction in costs of approximately $1,148 per LTCH annually or approximately $482,469 for all LTCHs annually. Also, as noted in section I.R. of this Appendix, the regulatory review cost for this proposed rule is $8,809,182.

Section of the proposed rule	Description	Amount of costs or savings
Section XIV.B.3. of the preamble	ICRs for the Hospital IQR Program	($71,233,624)
Section XIV.B.4. of the preamble	ICRs for the PCHQR Program	(1,013,595)
Section XIV.B.6. of the preamble	ICRs for the LTCH QRP	(482,469)
Section XIV.B.7. of the preamble	ICRs for the HAC Reduction Program *	1,580,256
Total		(72 million)

* We note that the net costs reflected in this table for the HAC Reduction Program do not constitute a new information collection requirement on participating hospitals, but a transition of the HAI measure validation process from one program to another based on our efforts to reduce measure duplication across programs.

Q. Overall Conclusion

1. Acute Care Hospitals

Overall, acute care hospitals are estimated to experience an increase of 3.4 percent, or approximately $4.1 billion, in their combined operating and capital payments as modeled for this proposed rule. Approximately 3.2 percentage points of this estimated increase is due to the proposed change in operating payments, including uncompensated care payments (discussed in sections I.G. and I.H. of this Appendix), approximately 0.1 percentage points is due to the proposed change in capital payments (discussed in section I.I of this Appendix), and approximately 0.1 percentage points is due to the proposed change in low-volume hospital payments (discussed in section I.H of this Appendix).

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 proposed wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 1.7 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 $146 million increase in capital payments in FY 2019 compared to FY 2018.

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 a decrease in estimated payments per discharge in FY 2019. 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 2019. Accordingly, based on the best available data for the 409 LTCHs in our database, we estimate that overall FY 2019 LTCH PPS payments would decrease approximately $5 million relative to FY 2018 as a result of the proposed payment rates and factors presented in this proposed rule.

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 the FY 2018 IPPS/LTCH PPS final rule (82 FR 38585), 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 recognized 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 the FY 2018 IPPS/LTCH PPS final rule (82 FR 38585), 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 2018 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 $105.16 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 19 hours for the staff to review half of the proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $1,998 (19 hours × $105.16). Therefore, we estimate that the total cost of reviewing this proposed rule is $8,809,182 ($1,998 × 4,409 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 the following Table V., 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 below in Table V., the net costs to the Federal Government associated with the proposed policies in this proposed rule are estimated at $4.1 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2018 TO FY 2019

Category	Transfers
Annualized Monetized Transfers.	$4.1 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 2019 relative to FY 2018 of approximately $5 million based on the data for 409 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., 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. 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 409 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. below, the net savings to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $5 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2018 LTCH PPS TO THE FY 2019 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	−$5 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

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 2019.'' 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.

In this proposed rule, 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 receive and our responses will be presented throughout the final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security 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. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the 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 2019, that threshold level is approximately $146 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. This proposed rule contains provisions 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 and, thus, has tribal implications. Therefore, in accordance with Executive Order 13175 and the CMS Tribal Consultation Policy (December 2015), CMS will consult with Tribal officials on these Indian-specific provisions of the proposed rule prior to the formal promulgation of this rule.

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 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 2019, consistent with our approach for FY 2018, 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 2019

A. Proposed FY 2019 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this proposed rule, for FY 2019, 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), and an additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2019 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38587), 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 with FY 2018.

In this FY 2019 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2019 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2017 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2017, which is estimated to be 2.8 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 2019 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2017 forecast, we are proposing an MFP adjustment of 0.8 percent for FY 2019. We also are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2019 market basket update and MFP adjustment for the final rule. Therefore, based on IGI's fourth quarter 2017 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 table below.

FY 2019	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	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.25	−0.85	0.55	−1.55

B. Proposed Update for SCHs and MDHs for FY 2019

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2019 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). As discussed in section IV.G. of the preamble of this proposed rule, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). 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.

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 table above for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2019 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 2019, we are proposing an applicable percentage increase of 1.25 percent to the standardized amount for hospitals located in Puerto Rico.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2019

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.A. of the preamble of this proposed rule, the update to the target amount for extended neoplastic disease care hospitals for FY 2019 would be the percentage increase in the 2014-based IPPS operating market basket. Accordingly, for FY 2019, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, 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 2019 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 2019 is 2.8 percent.

E. Proposed Update for LTCHs for FY 2019

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 the LTCH PPS standard Federal payment rate by 1.15 percent for FY 2019, consistent with the amendments to section 1886(m)(3) of the Act provided by section 411 of MACRA. 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 1.0115 in determining the LTCH PPS standard Federal rate for FY 2019. For LTCHs that fail to submit quality data for FY 2019, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of −0.85 percent (that is, the proposed annual update for FY 2019 of 1.15 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 0.9915 in determining the LTCH PPS standard Federal rate for FY 2019. (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 1.15 percent for FY 2019 does not reflect any proposed budget neutrality factors, such as the proposed offset for the elimination of the LTCH PPS 25-percent threshold policy.)

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update in the amount specified in current law for FY 2019. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, 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. 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 2.8 percent.

For FY 2019, 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 1.15 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2019, we are recommending an annual update to the LTCH PPS standard Federal rate of −0.85 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2018 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 in the amount specified in current law. We refer readers to

the March 2018 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on this recommendation.

Response: We agree with MedPAC, and consistent with current law, we are proposing to apply an applicable percentage increase for FY 2019 of 1.25 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are proposing to continue to use separate updates for operating and capital payments. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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Part III

Social Security Administration

20 CFR Parts 404 and 416
Revised Medical Criteria for Evaluating Musculoskeletal Disorders; Proposed Rule

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA–2006–0112]

RIN 0960–AG38

Revised Medical Criteria for Evaluating Musculoskeletal Disorders

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving musculoskeletal disorders in adults and children under titles II and XVI of the Social Security Act (Act). These proposed revisions reflect our adjudicative experience, advances in medical knowledge and treatment of musculoskeletal disorders, and recommendations from medical experts.

DATES: To ensure that your comments are considered, we must receive them no later than July 6, 2018.

ADDRESSES: You may submit comments by one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2006–0112 so that we may associate your comments with the correct regulation.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the *Search* function to find docket number SSA–2006–0112. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking (NPRM) is divided into several parts. First, we provide the supplementary information, which is often referred to as the preamble. In the preamble, we explain why we propose to revise the listings for the musculoskeletal body system and how we developed the proposed rules. We also offer a narrative of the changes we are proposing. The preamble tells the story behind the proposed rule changes, but if we decide to proceed with a final rule, the preamble will not become part of the Code of Federal Regulations.

The next section is the proposed revisions to the listing of impairments, located in Appendix 1 to Subpart P of 20 CFR part 404. For each body system affected by these proposed rules (*e.g.,* 1.00 Musculoskeletal Disorders), we first provide proposed changes to the introductory text (*e.g.,* 1.00A, B, C, etc.). If we decide to proceed with a final rule, the introductory text will become part of the Code of Federal Regulations. The introductory text details which disorders we evaluate and what evidence we need to conduct this evaluation. It also defines certain terms, and provides valuable background information. Individuals often refer to the introductory text for additional details related to a specific listing under which a medically determinable impairment (MDI) is being evaluated. After the introductory text, we provide specific listing text and criteria (*e.g.,* 1.15 and 1.16). The listings themselves provide specific criteria that an MDI must meet (or medically equal) in order for an individual to be found disabled under the listings.

I. Why are we proposing to revise the listings for the musculoskeletal body system?

We last published final rules that revised the musculoskeletal body system on November 19, 2001.[1] We are now proposing to update the introductory text and criteria in the current listings to reflect our adjudicative experience, advances in medical knowledge and treatment of musculoskeletal disorders, and comments and recommendations from medical experts.

While we believe our proposed revisions reflect advances in medical knowledge and treatment of musculoskeletal disorders, we are interested in receiving public comments on the following issues:

- Are there any musculoskeletal disorders that will meet one of the proposed listings, but are generally expected to medically improve after a certain amount of time to the point at which the disorders will no longer be of listing-level severity? If you believe there are musculoskeletal disorders that fit into this category, please tell us by submitting your comments and any supporting research or data. We will use your comments on this issue to inform our policy on the timing of continuing disability reviews.[2]
- Are the proposed functional criteria appropriate and sufficient for assessing listing level severity? If you believe the proposed functional criteria are either insufficient for documenting an impairment that meets a listing-level severity, or you believe these criteria will exclude eligible individuals with an impairment of listing-level severity, please tell us by submitting your comments and any supporting research or data.
- Did we remove or omit any valuable information that should be included in the introductory text? We intend for this text to ease administrative burdens for adjudicators, claimants, claimant representatives, and the public by clarifying terms, removing extraneous language, and providing guidance in an orderly fashion. If you believe we removed or omitted any valuable information, please tell us by submitting your comments and any supporting research or data.
- Should any of the proposed listings for musculoskeletal disorders be combined into one listing or divided into multiple listings for adjudicative ease and capture individuals with impairments that meet a listing-level severity? If you believe our listing categories create unnecessary administrative barriers for impairments that meet listing level severity, please

[1] 66 FR 58010. We also made a conforming change to the rules for musculoskeletal disorders when we published final rules revising the rules for immune system disorders on March 18, 2006 (73 FR 14570).

[2] See §§ 404.1590 and 416.990 of this chapter for our policy on when we will conduct a continuing disability review.

tell us by submitting your comments and any supporting research or data.

• Did we appropriately define ''close proximity of time'' in section 1.00C7 as meaning that all of the relevant criteria have to appear in the medical record within a period not to exceed 4 months of one another for musculoskeletal disorders? The 4-month threshold represents a period in which an individual receiving treatment for a chronic severe musculoskeletal impairment will undergo multiple examinations or treatments from their medical source(s). Individuals with chronic severe musculoskeletal impairments typically undergo multiple examinations or treatments. Therefore, we believe a 4-month threshold provides individuals with adequate time to receive multiple medical treatments documenting the existence of listing level criteria, should the relevant criteria exist. If you believe the ''close proximity of time'' should be defined by a different measure than 4 months, please tell us by submitting your comments and any supporting research or data.

• Based on advances in medical surgical, recuperative, and functionally restorative treatment of musculoskeletal disorders, would the proposed listing criteria allow us to adequately assess whether an individual has achieved ''maximum benefit from therapy'' or whether an individual is ''under continuing surgical management''? It is important that we do not encourage or incentivize individuals to increase their medical treatment to maintain or access disability benefits, particularly medical treatments that would likely be ineffective, or that may even be harmful, for the individual? If you believe ''the maximum therapeutic benefits'' criterion should be revised and evaluated by a different measure, please tell us by submitting your comments and any supporting research or data.

II. How did we develop these proposed rules?

As medicine and medical treatment are continuously evolving, we utilized well-known references such as the *Guides to the Evaluation of Permanent Impairment* from the American Medical Association, *Harrison's Principles of Internal Medicine, Current Diagnosis & Treatment in Orthopedics,* and *Nelson Textbook of Pediatrics* as a starting point to develop the proposed changes to these rules.[3] We also requested extensive input from our medical consultants (physicians employed by or who contract with us) who have years of experience practicing in relevant fields of medicine and who have intimate knowledge of our disability programs to develop our proposed changes to the musculoskeletal disorders listings. We rely on our medical consultants and their professional opinions based on their clinical experience and research to help us develop what criteria correspond with listing-level severity.

In developing our proposed rule changes, we used the resources above, our programmatic knowledge, our adjudicative experience, and the medical literature, such as *Archives of Physical Medicine and Rehabilitation, Journal of the American Academy of Orthopaedic Surgeons,* and *Hand Clinics.* These resources informed us of the most recent best practices and medical advancements and either support, or are consistent with, our proposed rule changes.

In addition to these distinguished medical sources and our medical consultants, in proposing these changes to the musculoskeletal disorders listings, we used information from:

• People who make and review disability determinations and decisions for us in State agencies, in our Office of Quality Review, and in our Office of Hearing Operations;

• Comments we received regarding the 2001 ''Final rules with request for comment,''[4] which we used as a starting point for identifying areas needing further research; and

• Additional published sources we list in the References section at the end of this preamble, including the National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division (formerly the Institute of Medicine).

III. What major revisions are we proposing?

We propose to revise both the content and the structure of the adult and childhood musculoskeletal disorders listings and introductory texts as follows:

• Provide uniform and specific severity criteria for evaluating the effects of a musculoskeletal disorder on a person's functioning;

• Revise the introductory texts in 1.00 *Musculoskeletal Disorders* and 101.00 *Musculoskeletal Disorders* to provide guidance on the specific severity criteria;

• Add specific sections in the introductory texts in 1.00 *Musculoskeletal Disorders* and 101.00 *Musculoskeletal Disorders* to provide guidance on each listing;

• Revise the content and structure of the current listings to incorporate the new severity criteria into each listing;

• Add listings for evaluating pathologic fractures due to any cause (1.19 *Pathologic fractures due to any cause* for adults and 101.19 *Pathologic fractures due to any cause* for children);

• Add a child listing for evaluating musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay (101.24 *Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay*);

• Use the same general structure in most adult and child listings, consisting of symptoms, signs, laboratory findings, and applicable functional criteria, in that order;

• Remove current 1.02 and 101.02 *Major dysfunction of a joint(s) (due to any cause)* and incorporate the provisions in proposed 1.18 and 101.18 *Abnormality of a major joint(s) in any extremity;*

• Remove current 1.04 *Disorders of the spine* and 1.04A ''Evidence of nerve root compression,'' and incorporate the provisions of 1.04A in proposed 1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s);*

• Remove current 1.04B ''Spinal arachnoiditis'' because it is a secondary effect, rather than a primary skeletal spine disorder, which can be evaluated under proposed 1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina;*

• Remove current 1.04C ''Lumbar spinal stenosis,'' and incorporate its provisions in proposed 1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina;*

• Remove current 101.04 *Disorders of the spine* and incorporate the provisions in proposed 101.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s)* and 101.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina;*

• Remove current 1.05 and 101.05 *Amputation (due to any cause),* and incorporate its provisions in proposed 1.20 and 101.20 *Amputation due to any cause;*

• Remove current 1.06 and 101.06 *Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones;* and incorporate the provisions of those listings in proposed 1.22 and 101.22 *Non-healing or complex fracture of the*

[3] Full citations are available in X. *References* below.

[4] The final rules with request for comments are available at *http://www.gpo.gov/fdsys/pkg/FR-2001-11-19/pdf/01-28456.pdf.* Comments on the final rules may be found at *http://www.regulations.gov/,* and search for ''SSA–2006–0112''.

femur, tibia, pelvis, or one or more of the tarsal bones;

- Remove current 1.07 and 101.07 *Fracture of an upper extremity;* and incorporate the provisions of those listings in proposed 1.23 and 101.23 *Non-healing or complex fracture of an upper extremity;* and
- Remove current 1.08 and 101.08 *Soft tissue injury (e.g., burns),* and incorporate the provisions in proposed 1.21 and 101.21 *Soft tissue injury or abnormality under continuing surgical management.*

IV. What changes are we proposing to the introductory text of the musculoskeletal disorders listings for adults?

We propose to adopt a question-and-answer framework to make the guidance contained in the introduction easier for adjudicators, claimants, claimant representatives, and the public to locate, and to make the introductory text consistent with the format used in other body systems.

We propose to remove the phrases ''loss of function'' and ''functional loss'' and replace the content of current 1.00B1 *General,* 101.00B1 *General,* 1.00B2 *How we define loss of function in these listings,* and 101.00B2 *How We Define Loss of Function in These Listings.* We are replacing the content of 1.00B1 *General* and 101.00B1 *General* because it may be read to imply that we require an absence of function in order to evaluate an impairment under these listings. Except in the case of amputation, the proposed listings do not require a complete absence of function. In 1.00B2 *How We Define Loss of Function in These Listings* and 101.00B2 *How We Define Loss of Function in These Listings,* we are removing the descriptive phrases, ''inability to ambulate effectively,'' ''extreme limitation of the ability to walk,'' ''interferes very seriously with the individual's ability to independently initiate, sustain, or complete activities,'' ''ineffective ambulation,'' and ''independent ambulation,'' along with the corresponding examples in that paragraph. We are replacing these descriptors with uniform and specific severity criteria, which we believe will provide clearer guidance for adjudicators and the public.

We propose to provide new uniform and specific functional criteria, which we describe in the introductory text for each listing, for evaluating the severity of limitations caused by musculoskeletal disorders. We chose these particular functional criteria because they clearly illustrate the level of dysfunction for upper and lower extremities that would cause an adult to be unable to work, or that would cause a child to be unable to perform age-appropriate activities. The effects of a particular disorder on musculoskeletal functioning, and the treatment needed, direct which of these criteria are appropriate for each of the listings. The functional criteria for adults are as follows:

1. A documented medical need for a walker, bilateral canes, or bilateral crutches;

2. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

In developing this uniform and specific severity criteria, we utilized medical resources, such as ''Ambulatory Assistive Devices in Orthopaedics: Uses and Modifications,'' [5] the professional experience of our medical consultants, information related to workplace functioning from the Bureau of Labor Statistics, and our adjudicative experience. Each of these criteria illustrate restrictions of multiple extremities and thus, significant limitations.

We propose to explain each proposed listing in separate sections of the introduction.

The following chart shows the headings of the current and proposed sections of the adult introductory text:

Current introductory text	Proposed introductory text
A. *Disorders of the musculoskeletal system*	A. *Which disorders do we evaluate under these listings?*
B. *Loss of function*	B. *Which related disorders do we evaluate under other listings?*
C. *Diagnosis and Evaluation*	C. *What evidence do we need to evaluate your musculoskeletal disorder under these listings?*
D. *The physical examination*	D. *How do we consider symptoms, including pain, under these listings?*
E. *Examination of the Spine*	E. *How do we use the functional criteria under these listings?*
F. *Major joints*	F. *What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (1.15)?*
G. *Measurements of joint motion*	G. *What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (1.16)?*
H. *Documentation*	H. *What do we consider when we evaluate reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (1.17)?*
I. *Effects of Treatment*	I. *What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?*
J. *Orthotic, Prosthetic, or Assistive Devices*	J. *What do we consider when we evaluate pathologic fractures due to any cause (1.19)?*
K. *Disorders of the spine*	K. *What do we consider when we evaluate amputation due to any cause (1.20)?*
L. *Abnormal curvatures of the spine*	L. *What do we consider when we evaluate soft tissue injury or abnormality under continuing surgical management (1.21)?*
M. *Under continuing surgical management*	M. *What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the tarsal bones (1.22)?*
N. *After maximum benefit from therapy has been achieved*	N. *What do we consider when we evaluate non-healing or complex fractures of an upper extremity (1.23)?*

[5] Full citation is available in X. *References,* below.

Current introductory text	Proposed introductory text
O. *Major function of the face and head*	O. *How do we determine when your soft tissue injury or abnormality, or your upper extremity fracture, is no longer under continuing surgical management or you have received maximum therapeutic benefit?*
P. *When surgical procedures have been performed*	P. *How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment?*
Q. *Effects of obesity*	Q. *How do we evaluate substance use disorders that co-exist with musculoskeletal disorders?*
	R. *How do we evaluate disorders that do not meet one of the musculoskeletal listings?*

Proposed 1.00—Introduction

The following is a detailed description of the changes we propose to the introductory text.

Proposed 1.00A—Which disorders do we evaluate under these listings?

We propose to revise current 1.00A *Disorders of the musculoskeletal system* to explain that we evaluate musculoskeletal disorders that result in dysfunction of the skeletal spine or of the upper or lower extremities,[6] fractures, and soft tissue [7] abnormalities or injuries that are under continuing surgical management.

We begin with listings for disorders affecting functioning of the skeletal spine, because our adjudicative experience shows that these are the most frequently used listings in this body system.

Proposed 1.00B—Which related disorders do we evaluate under other listings?

We propose to replace the content of current 1.00B *Loss of function* with improved guidance for disorders that affect musculoskeletal functioning, which we evaluate under other listings. We explain that we evaluate injuries of the skeletal spine resulting in dysfunction of the spinal cord under 11.00 *Neurological Disorders,* and we evaluate inflammatory arthritis under 14.00 *Immune System Disorders.* We state that we evaluate abnormal curvatures of the spine that adversely affect functioning in other body systems under the appropriate listing in the affected body system. We have removed the guidance from current 1.00L that states ''Abnormal curvatures of the spine (specifically, scoliosis, kyphosis and kyphoscoliosis) can result in impaired ambulation, but may also adversely affect functioning in body systems other than the musculoskeletal system.'' Instead, we propose to evaluate spinal curvatures that affect musculoskeletal functioning under proposed 1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s),* depending on the area of dysfunction created by the curvature. We also state that we can evaluate a curvature of the spine that is under continuing surgical management under proposed 1.21 *Soft tissue injury or abnormality under continuing surgical management.*

Proposed 1.00C—What evidence do we need to evaluate your musculoskeletal disorder under these listings?

We propose to replace current 1.00C *Diagnosis and Evaluation* with a comprehensive explanation of the information and evidence we need to evaluate musculoskeletal disorders. Once we establish the disorder, we evaluate evidence from medical and non-medical sources to assess severity and duration under the musculoskeletal listings. We describe the elements needed in a physical examination report. We discuss laboratory and other test findings and their usefulness and limitations, and we explain our policy concerning evaluation of imaging and other diagnostic tests. We discuss our need for operative reports and what we will accept in the absence of such reports, incorporating the guidance from current introductory section 1.00P *When surgical procedures have been performed.* We identify the evidence we need concerning a person's treatment and response to it.

In section 1.00C6 *Assistive devices,* we clarify what we mean by a prosthesis(es) and an orthosis(es). We discuss the evidence we need when a person with a musculoskeletal disorder uses an assistive device(s), including a cane(s), crutch(es), walker, prosthesis(es), or orthosis(es).

In section 1.00C7 *Longitudinal evidence,* we explain the importance of a longitudinal medical record in determining whether a musculoskeletal disorder satisfies the duration requirement. We explain that, for all listings except 1.19 *Pathologic fractures due to any cause,* 1.20A ''Amputation of both upper extremities'' 1.20B ''Hemipelvectomy or hip disarticulation'', and 1.21 *Soft tissue injury or abnormality under continuing surgical management,* all listing criteria must be present simultaneously, or within a close proximity of time; and must have lasted, or be expected to last, for a continuous period of at least 12 months for a disorder to meet a listing.

In section 1.00C *What evidence do we need to evaluate your musculoskeletal disorder under these listings?,* we clarify that, when the listing criteria are linked by the word ''and'' (whether in small case or capital case), the requirements must be simultaneously present, or present within a ''close proximity of time,'' which we define in section 1.00C7 as meaning that all of the relevant criteria have to appear in the medical record within a period not to exceed 4 months of one another. Consistent with the standard of care and common industry practice, according to our medical consultants, literature review, and external medical experts, such as those from the Health and Medicine Division at the National Academies of Science Engineering and Medicine, an individual receiving treatment for a chronic severe musculoskeletal impairment will typically receive treatment or undergo examination at least once every 3 months. Should an individual meet an applicable listing, the listing criteria is likely to be documented every third month. The 4-month threshold provides leeway in cases where a physical examination might not be performed or symptoms are not documented at a given appointment. The 4-month threshold represents a period in which individuals receiving treatment for a chronic severe musculoskeletal impairment will undergo multiple examinations or treatments from their medical source(s), providing a window encompassing multiple medical

[6] Impairments involving the shoulders will typically affect upper extremities while the impairments involving the pelvis, hips, and ribs typically affect lower extremities. When assessing dysfunction, the resultant incapacity or limitation is key to assessing the impairment under the applicable medical listing.

[7] Soft tissue refers to non-skeletal tissues that make up a large percentage of the body, such as the tendons, ligaments, fascia and muscles.

appointments over which applicable listing criteria can be adequately documented. The 4-month threshold does not apply to imaging.

We propose to add this clarification to address a holding in *Radford* v. *Colvin,* 734 F.3d 288 (4th Cir. 2013) with respect to current 1.04A *Disorders of the spine,* ''Evidence of nerve root compression.'' The *Radford* Court held that ''[a] claimant need not show that each symptom was present at precisely the same time—*i.e.,* simultaneously—in order to establish the chronic nature of his condition. Nor need a claimant show that the symptoms were present in the claimant in particularly close proximity.'' [8]

Because this holding of the *Radford* Court differed from our interpretation of the listing requirement, we issued Acquiescence Ruling (AR) 15–1(4) to implement the Court of Appeals holding within the States in the Fourth Circuit.[9] We now propose to clarify our longstanding interpretation of the regulations in response to the *Radford* decision. We also propose to clarify that this policy applies to other listings that have similar requirements.

The issuance of a new regulation to address a holding of a Court of Appeals that conflicts with our policy is consistent with the process described in our regulations for issuing and rescinding Acquiescence Rulings. Our regulations specifically contemplate that we may ''subsequently publish a new regulation(s) addressing an issue(s) not previously included in our regulations when that issue(s) was the subject of a circuit court holding that conflicted with our interpretation of the Social Security Act or regulations and that holding was not compelled by the statute or Constitution.'' 20 CFR 404.985(e)(4), 416.1485(e)(4). After we have considered the public comments in response to these proposed rules and issued any final rules, we will decide whether we need to rescind the *Radford* AR.

Section 1.00C8 *Surgical treatment,* discusses how we evaluate surgical treatment. We explain when and why we may wait to receive additional evidence before making a determination of disability.

Proposed 1.00D—How do we consider symptoms, including pain, under these listings?

We propose to replace current 1.00D *The physical examination* with guidance about how we consider symptoms of musculoskeletal impairments, particularly pain. We explain that your pain must be supported by medical signs and laboratory findings, established by medically acceptable clinical, laboratory, or diagnostic techniques, showing the existence of a medical impairment(s) which results from anatomical, physiological, or psychological abnormalities.

Proposed 1.00E—How do we use the functional criteria under these listings?

We propose to replace current 1.00E *Examination of the Spine* with new guidance about how we use the functional criteria to evaluate musculoskeletal disorders under these listings. We explain what we mean by functional criteria, we list the criteria, and we explain why listings 1.20A 'Amputation of both upper extremities'', 1.20B ''Hemipelvectomy or hip disarticulation'' and 1.21 *Soft tissue injury or abnormality under continuing surgical management* do not include the functional criteria. We also explain that we will evaluate a person's functioning with respect to the work environment, rather than the home environment, because the ability to walk independently about one's home without the use of assistive devices does not, in and of itself, indicate an ability to walk without an assistive device in a work environment. We explain that in order to be disabling, a musculoskeletal disorder must satisfy the medical criteria as well as the 12-month duration requirement and, where applicable, must include at least one of the functional criteria of a listing.

Proposed 1.00F—What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (1.15)?

We propose to replace the content of current 1.00F *Major joints* with guidance regarding how we evaluate disorders of the skeletal spine under proposed 1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s).* In proposed 1.00F, we list the various spinal disorders that result in compromise of nerve roots; we explain the symptoms and signs associated with those disorders; and we explain how a medical source evaluates those symptoms and signs in clinical examinations.

Proposed 1.00G—What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (1.16)?

We propose to replace the content of current 1.00G *Measurements of joint motion* with guidance about how we evaluate the effects of compromise of the cauda equina due to lumbar spinal stenosis under proposed 1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina.* We explain how lumbar spinal stenosis can compromise the cauda equina; we provide a more detailed discussion of the cauda equina and associated symptoms and signs; and we explain how the disorder affects functioning. We also explain the difference between pain caused by compromise of the cauda equina (neurogenic claudication or pseudoclaudication) and pain caused by peripheral arterial disease (vascular claudication).

Proposed 1.00I—What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?

We propose to replace the content of current 1.00I *Effects of Treatment* with guidance about how we evaluate abnormality in a major joint(s) under proposed 1.18 *Abnormality of a major joint(s) in any extremity.* We explain how we define abnormalities of the joints, and give specific examples of the types of diseases, injuries, and other conditions that may contribute to joint dysfunction. We also explain how these disorders interfere with functions of the extremities.

Proposed 1.00J—What do we consider when we evaluate pathologic fractures due to any cause (1.19)?

We propose to replace the content of current 1.00J *Orthotic, Prosthetic, or Assistive Devices* with guidance regarding how we evaluate pathologic fractures under proposed new 1.19 *Pathologic fractures due to any cause.* We explain what we mean by ''pathologic fractures;'' we state that these types of fractures can affect the skeletal spine, extremities, or other parts of the skeletal system; we give examples of disorders that can cause pathologic fractures; and we explain how we evaluate their occurrence and recurrence.

Proposed 1.00K—What do we consider when we evaluate amputation due to any cause (1.20)?

We propose to replace the content of current 1.00K *Disorders of the spine* with guidance about how we evaluate amputation due to any cause under proposed 1.20 *Amputation due to any*

[8] 734 F.3d at 294.

[9] 80 FR 57418 (2015). Available at: *https://www.ssa.gov/OP_Home/rulings/ar/04/AR2015-01-ar-04.html.*

cause. We explain that we evaluate amputations involving upper or lower extremities and combinations of those extremities, as well as hemipelvectomies and hip disarticulations. We explain that when a person has amputations of one upper extremity at any level above the wrist and one lower extremity at or above the ankle, we consider whether the person has a documented medical need for a one-handed assistive device. We also explain how we consider amputation of one or both lower extremities at or above the ankle (tarsal joint). We state that we use this listing when a person has residual limb complications that have lasted, or are expected to last, for at least 12 months, and the person is not currently undergoing surgical management.

Proposed 1.00L—What do we consider when we evaluate soft tissue injury or abnormality under continuing surgical management (1.21)?

We propose to replace the content of current 1.00L *Abnormal curvatures of the spine* with guidance about how we evaluate soft tissue abnormality or injury of any part of the body that is under continuing surgical management. We also incorporate the provisions of current sections 1.00M *Under continuing surgical management,* 1.00N *After maximum benefit from therapy has been achieved,* 1.00O *Major function of the face and head,* and 1.00P *When surgical procedures have been performed.* We explain that we use proposed 1.21 *Soft tissue injury or abnormality under continuing surgical management* to evaluate any soft tissue abnormality or injury, whether congenital or acquired, including malformations, third- and fourth-degree burns, craniofacial injuries, avulsive injuries, amputations with complications of the residual limb(s), and complications of non-healing or complex traumatic fractures. We explain that a person must have a documented medical need for a continuing series of ongoing surgical procedures and associated medical treatments, directed toward saving, reconstructing, or replacing the affected part of the body. We further explain that these treatments must have been, or must be expected to be, ongoing for a continuous period of least 12 months. We list the clinical evidence we need to determine whether a disorder meets this listing. We explain how we evaluate third- and fourth-degree burns and craniofacial injuries. We also explain how we evaluate when maximum therapeutic benefit has occurred and how we evaluate residual impairment.

Proposed 1.00M—What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the tarsal bones (1.22)?

We propose to replace the content of current 1.00M *Under continuing surgical management* with guidance about how we evaluate non-healing or complex fractures involving bones in the lower extremity. We also provide definitions for ''non-healing fracture'' and ''complex fracture.''

Proposed 1.00N—What do we consider when we evaluate non-healing or complex fractures of an upper extremity (1.23)?

We propose to replace the content of current 1.00N *After maximum benefit from therapy* with guidance about how we evaluate non-healing or complex fractures involving bone in the upper extremity. We also provide definitions for ''non-healing fracture'' and ''complex fracture.''

Proposed 1.00O—How do we determine your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management or you have received maximum therapeutic benefit?

We propose to replace the content of current 1.00O *Major function of the face and head* with guidance about determining when a soft tissue injury or abnormality or upper extremity fracture is no longer under continuing surgical management. We also incorporate the provisions of current sections 1.00M *Under continuing surgical management,* 1.00N *After maximum benefit from therapy has been achieved,* and 1.00P *When surgical procedures have been performed.*

Proposed 1.00P—How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment?

We propose to replace the content of current 1.00P *When surgical procedures have been performed* with guidance about how we assess impairments when there is no longitudinal medical record. We explain that when the individual has not received ongoing treatment or has just begun treatment, we may ask the individual to attend a consultative examination. We also explain that we may be able to assess the severity and duration of the individual's impairment based on the medical record and current evidence alone. In this section, we incorporate guidance from current section 1.00H3 *When there is no record of ongoing treatment.*

Proposed 1.00R—How do we evaluate disorders that do not meet one of the musculoskeletal listings?

We propose to add a new section 1.00R with guidance explaining that if a person's disorder does not meet or medically equal the criteria of any of these listings, we will consider whether it meets or medically equals the criteria for a listing in another body system. We explain that if an impairment does not meet or medically equal any listing, we will assess the person's residual functional capacity (RFC) and determine whether the person is capable of performing past work or adjusting to other work in the national economy. We also cite the rules we use when we determine whether a person continues to be disabled. In this section, we incorporate guidance from current section 1.00H4 *Evaluation when the criteria of a musculoskeletal listing are not met.*

V. What changes are we proposing to the musculoskeletal listings for adults?

We propose to revise the name of the body system from ''Musculoskeletal System'' to ''Musculoskeletal Disorders.''

We propose to rename the headings of the listings and to renumber the listings in a more logical order, beginning with disorders of the spine, as those are the most frequently used; moving outward physically to the extremities; and then to skeletal or soft tissue injuries. When these rules become final, renumbering the listings should make it easier for us to keep track of data trends for specific types of impairments over time. It should also help to prevent confusion in identifying or referring to prior listings after we publish a final rule.

We propose to present the overall structure of the listings in an outline form to make the rules more readily accessible to the reader. The following chart provides a comparison of the current and the proposed adult listings:

Current listing	Proposed listing
1.02 *Major dysfunction of a joint(s) (due to any cause)*	1.02 Removed without replacement.
1.03 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.*	1.03 Removed without replacement.
1.04 *Disorders of the spine*	1.04 Removed without replacement.
1.05 *Amputation (due to any cause)*	1.05 Removed without replacement.
1.06 *Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.*	1.06 Removed without replacement.
1.07 *Fracture of an upper extremity*	1.07 Removed without replacement.
1.08 *Soft tissue injury (e.g., burns)*	1.08 Removed without replacement.
	1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s).*
	1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina.*
	1.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.*
	1.18 *Abnormality of a major joint(s) in any extremity.*
	1.19 *Pathologic fractures due to any cause.*
	1.20 *Amputation due to any cause.*
	1.21 *Soft tissue injury or abnormality under continuing surgical management.*
	1.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones*
	1.23 *Non-healing or complex fracture of an upper extremity.*

All of the proposed musculoskeletal listings contain multiple criteria. We distinguish whether all of the criteria must be met in order to meet that specific listing or just one of the criteria must be met in order to meet that specific listing by using a capital ''AND'' or ''OR,'' respectively. The ''AND'' or ''OR'' sit on a line independently on the left margin. We also distinguish whether all sub-criteria must be met or just one of the sub-criteria must be met in order to satisfy the relevant criteria by using a lowercase ''and'' or ''or,'' respectively.

1.15 Disorders of the Skeletal Spine Resulting in Compromise of a Nerve Root(s)

Proposed 1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s)* incorporates and clarifies the provisions of current 1.04A for evidence of nerve root compression. In proposed 1.15 we have removed references to the particular disorders associated with compromise of a nerve root(s) and discussion of the tests used to demonstrate them. We have incorporated the references to specific disorders in the introductory text because they are examples of possible causative agents, whereas the listing addresses the effects of those agents on the nerve root(s). We have also removed the sign of atrophy from the listing because medical research and our experience does not show atrophy necessarily correlates with any given level of functioning. We have provided for consideration of limitation of motion by evaluating the physical limitation of musculoskeletal functioning it causes using the new functional criteria. Under proposed criterion 1.15B for radicular neurological signs, we have included muscle weakness and sensory changes. We have also added the requirement for ''[d]ecreased deep tendon reflexes'' to the criterion because it is a manifestation of the disorder and illustrates our intentions for this listing. A criterion for imaging, which is not explicitly required in current 1.04A, has been added as proposed 1.15C ''Findings on imaging consistent with compromise of a nerve root(s)'' because it is a component necessary to establishing the disorder.

1.16 Lumbar Spinal Stenosis Resulting in Compromise of the Cauda Equina

Proposed 1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina* incorporates and clarifies the provisions of current 1.04C for lumbar spinal stenosis resulting in pseudoclaudication. We incorporate each of the requirements in current 1.04C into sections A–D of the proposed listing and clarify the current requirements with specific information in sections A–C. We have made a separate listing for compromise of the cauda equina due to the effects of lumbar spinal stenosis, because the symptoms and signs of this disorder differ from those of other nerve root(s) disorders and are not typically associated with a specific nerve root(s).

1.17 Reconstructive Surgery or Surgical Arthrodesis of a Major Weight-Bearing Joint

Proposed 1.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint* incorporates and clarifies the provisions of current listing 1.03 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.*

1.18 Abnormality of a Major Joint(s) in Any Extremity

Proposed 1.18 *Abnormality of a major joint(s) in any extremity* incorporates and clarifies the provisions of current listings 1.02 *Major dysfunction of a joint(s) (due to any cause).* It includes the criteria from current 1.02 for evaluating dysfunction of any of the major joints in either the upper or lower extremities, or both, whether due to anatomical deformity, pain, or abnormal motion. We removed the terms ''peripheral'' and ''weight-bearing,'' which are in the current listing for major joint disorders (1.02 *Major dysfunction of a joint(s) (due to any cause)),* because proposed 1.18 covers all major joints in any extremity, making those distinctions unnecessary.

1.19 Pathologic Fractures Due to Any Cause

Proposed 1.19 *Pathologic fractures due to any cause* is a new listing that covers pathologic fractures of any part of the musculoskeletal system. Medical treatment and recovery expectations for fractures differ, depending on whether the condition is due to an underlying pathology (such as osteoporosis), or to a traumatic event. For this reason, we propose a separate listing for fractures caused by an underlying pathology in order to provide specific criteria related to their evaluation and adjudication. We propose to evaluate complex or non-

healing traumatic fractures under proposed 1.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones* or 1.23 *Non-healing or complex fracture of an upper extremity.*

1.20 Amputation Due to Any Cause

Proposed 1.20 *Amputation due to any cause* incorporates and clarifies the provisions of current 1.05 *Amputation (due to any cause).* Proposed 1.20B for hemipelvectomy or hip disarticulation corresponds to current 1.05D for hemipelvectomy or hip disarticulation. In proposed 1.20A for amputation of both upper extremities and 1.20B for hemipelvectomy or hip disarticulation, we do not include any functional criteria, because we presume that a person with a disorder under either proposed 1.20A or 1.20B has limitations that satisfy one or more of the functional criteria in 1.00E2 and meet the duration requirement.

1.21 Soft Tissue Injury or Abnormality Under Continuing Surgical Management

Proposed 1.21 *Soft tissue injury or abnormality under continuing surgical management* revises current listing 1.08 *Soft tissue injury (e.g., burns).* This proposed listing is consistent with our long-standing recognition that extensive, prolonged treatment in order to re-establish or improve function of the affected body part(s) may contribute to an inability to perform work-related activity.

It encompasses any abnormality of, or injury (including burns) to soft tissue that is under continuing surgical management directed toward saving, reconstructing, or replacing the affected part of the body. In proposed 1.21, we do not include any functional criteria because the prescribed surgical procedures treatments typically require a series of documented interventions over extended periods, which render the person unable to perform work-related activity on a sustained basis.

1.22 Non-Healing or Complex Fracture of the Femur, Tibia, Pelvis, or One or More of the Tarsal Bones

Proposed 1.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones* incorporates and clarifies the provisions of current listing 1.06 *Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.*

1.23 Non-Healing or Complex Fracture of an Upper Extremity

Proposed 1.23 *Non-healing or complex fracture of an upper extremity* incorporates and clarifies the provisions of current listing 1.07 *Fracture of an upper extremity.*

VI. What changes are we proposing to the introductory text of the musculoskeletal disorders listings for children?

The same basic rules for evaluating musculoskeletal disorders in adults apply to the evaluation of such disorders in children. Except for changes in the introductory text specific to children, we propose to repeat most of the introductory text of proposed 1.00 *Musculoskeletal Disorders* in the introductory text of proposed 101.00 *Musculoskeletal Disorders.* Since we have already described these proposed revisions in the introductory text of proposed 1.00, we describe here only those sections of the proposed 101.00 rules that are unique to children or that require further explanation.

The following chart shows the headings of the current and proposed sections of the childhood introductory text:

Current introductory text	Proposed introductory text
A. *Disorders of the musculoskeletal system*	A. *Which disorders do we evaluate under these listings?*
B. *Loss of Function*	B. *Which related disorders do we evaluate under other listings?*
C. *Diagnosis and Evaluation*	C. *What evidence do we need to evaluate your musculoskeletal disorder under these listings?*
D. *The physical examination*	D. *How do we consider symptoms, including pain, under these listings?*
E. *Examination of the Spine*	E. *How do we use the functional criteria under these listings?*
F. *Major joints*	F. *What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (101.15)?*
G. *Measurements of joint motion*	G. *What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (101.16)?*
H. *Documentation*	H. *What do we consider when we evaluate reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (101.17)?*
I. *Effects of Treatment*	I. *What do we consider when we evaluate abnormality of a major joint(s) in any extremity (101.18)?*
J. *Orthotic, Prosthetic, or Assistive Devices*	J. *What do we consider when we evaluate pathologic fractures due to any cause (101.19)?*
K. *Disorders of the spine*	K. *What do we consider when we evaluate amputation due to any cause (101.20)?*
L. *Abnormal curvatures of the spine*	L. *What do we consider when we evaluate soft tissue injury or abnormality under continuing surgical management (101.21)?*
M. *Under continuing surgical management*	M. *What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the tarsal bones (101.22)?*
N. *After maximum benefit from therapy has been achieved*	N. *What do we consider when we evaluate non-healing or complex fractures of an upper extremity (101.23)?*
O. *Major function of the face and head*	O. *What do we consider when we evaluate musculoskeletal disorders of infants and toddlers from birth to attainment of age 3 with developmental motor delay (101.24)?*
P. *When surgical procedures have been performed*	P. *How do we determine when your soft tissue injury or abnormality, or your upper extremity fracture, is no longer under continuing surgical management or you have received maximum therapeutic benefit?*
	Q. *How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment?*
	R. *How do we evaluate disorders that do not meet one of the musculoskeletal listings?*

VII. What changes are we proposing to the musculoskeletal disorders listings for children?

We propose to revise the name of the body system from ''Musculoskeletal System'' to ''Musculoskeletal Disorders.''

We propose to add 101.24 *Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay.* This listing evaluates developmental motor delay due to a musculoskeletal medically determinable impairment as a functional criterion for infants and toddlers. We propose to move the requirement of developmental motor skills that are no greater than one-half of the expected age performance from current 101.00B2c(2) *How we assess inability to perform fine and gross movements in very young children* into proposed 101.24. Proposed 101.24 does not have an adult counterpart.

We propose to use functional criteria for children that are the same as the criteria for adults.

The following chart provides a comparison of the current childhood listings and the proposed childhood listings:

Current childhood listings	Proposed childhood listings
101.02 *Major dysfunction of a joint(s) (due to any cause)*	101.02 Removed without replacement.
101.03 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.*	101.03 Removed without replacement.
101.04 *Disorders of the spine*	101.04 Removed without replacement.
101.05 *Amputation (due to any cause)*	101.05 Removed without replacement.
101.06 *Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.*	101.06 Removed without replacement.
101.07 *Fracture of an upper extremity*	101.07 Removed without replacement.
101.08 *Soft tissue injury (e.g., burns)*	101.08 Removed without replacement.
	101.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s).*
	101.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina.*
	101.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.*
	101.18 *Abnormality of a major joint(s) in any extremity.*
	101.19 *Pathologic fractures due to any cause.*
	101.20 *Amputation due to any cause.*
	101.21 *Soft tissue injury or abnormality under continuing surgical management.*
	101.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.*
	101.23 *Non-healing or complex fracture of an upper extremity.*
	101.24 *Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay.*

As is the case with adults, for children, all of the proposed musculoskeletal listings contain multiple criteria. We distinguish whether all of the criteria must be met in order to meet that specific listing or just one of the criteria must be met in order to meet that specific listing by using a capital ''AND'' or ''OR,'' respectively. The ''AND'' or ''OR'' sit on a line independently on the left margin. We also distinguish whether all sub-criteria must be met or just one of the sub-criteria must be met in order to satisfy the relevant criteria by using a lowercase ''and'' or ''or,'' respectively.

VIII. Other Changes

We propose to make conforming changes to current sections 4.00G4 *What is lymphedema and how will we evaluate it?* and 104.00F9 *What is lymphedema and how will we evaluate it?* of the cardiovascular system listings to indicate that we may evaluate whether lymphedema medically equals proposed listings 1.18 and 101.18 *Abnormality of a major joint(s) in any extremity.*

We propose to make conforming changes to the introductory text and listing criteria for immune system disorders. Many disorders of the immune system affect the musculoskeletal system; therefore, we are making these revisions to reflect this relationship and ensure consistency in our evaluation of musculoskeletal functioning. In 14.00C *Definitions* and 114.00C *Definitions,* we propose to provide explanations of terms for evaluating immune system disorders consistent with those we propose for evaluating musculoskeletal disorders. We propose to add definitions for ''assistive device(s),'' ''documented medical need,'' ''fine and gross movements,'' and ''hand-held assistive device.'' We also propose to replace ''major peripheral joints'' with ''major joint of an upper or lower extremity,'' to revise the explanation of that term, and to remove the terms ''inability to ambulate effectively'' and ''inability to perform fine and gross movements effectively'' for consistency with the proposed musculoskeletal disorders listings.

We propose to revise the information in current sections 14.00D4 *Polymyositis and dermatomyositis (14.05)* and 114.00D4 ''*Polymyositis and dermatomyositis (114.05)*'' describing how we evaluate polymyositis and dermatomyositis in motor skills of newborns, younger infants, children, and adults. We propose to revise these sections for consistency with the proposal to remove the term ''unable to ambulate effectively.'' We propose to replace ''ambulate effectively'' with ''walk without physical or mechanical assistance.''

We propose to make editorial changes to current sections 14.00D6 *Inflammatory arthritis (14.09)* and 114.00D6 *Inflammatory arthritis (114.09).* We propose to replace ''major peripheral joints'' with ''major joints in an upper or lower extremity,'' ''ambulation or fine and gross movements'' with ''walking or performing fine and gross movements,'' and ''ambulation or the performance of fine and gross movements'' with ''walking or performing fine and gross movements.''

We propose to make conforming changes to describe listing-level severity in proposed listing criteria 14.09A and 114.09A ''Persistent inflammation or persistent deformity'' as follows: we propose to replace ''an impairment that results in an 'extreme' (very serious) limitation'' with ''the presence of an impairment-related, significant limitation cited in the criteria of these listings.'' We propose to replace ''one major peripheral weight-bearing joint resulting in the inability to ambulate effectively'' with ''one major joint in a lower extremity resulting in a documented medical need for a walker, bilateral canes, or bilateral crutches.'' We propose to replace ''one major peripheral joint in each upper extremity resulting in the inability to perform fine and gross movements effectively'' with ''one major joint in each upper extremity resulting in an impairment-related, significant limitation in the ability to perform fine and gross movements.''

To describe listing-level severity in current listing criteria 14.09C and 114.09 C ''Ankylosing spondylitis or other spondyloarthropathies'' we propose to replace ''extreme limitation'' with ''impairment-related significant limitation'' and ''inability to ambulate effectively'' with ''a documented medical need for a walker, bilateral canes, or bilateral crutches.''

To describe listing-level severity in current listing criteria 14.09B, C, and D and 114.09B and C for impairments due to inflammatory arthritis, we also propose to replace ''major peripheral joints'' with ''major joints in an upper or lower extremity.''

We propose to revise current section 114.00J2b ''Musculoskeletal involvement, such as surgical reconstruction of a joint, under 101.00'' to indicate that we may evaluate immune system disorders in children involving developmental motor delay under 101.00 *Musculoskeletal Disorders.*

We propose conforming changes to current immune system disorders listings 14.04 *Systemic sclerosis (scleroderma),* 14.05 *Polymyositis and dermatomyositis,* 14.09 *Inflammatory arthritis,* 114.04 *Systemic sclerosis (scleroderma),* 114.05 *Polymyositis and dermatomyositis* and 114.09 *Inflammatory arthritis.* In proposed 14.04 *Systemic sclerosis (scleroderma),* 14.05 *Polymyositis and dermatomyositis,* and 14.09 *Inflammatory arthritis* for adults, we would replace ''inability to ambulate effectively'' with the requirement of one of the following:

- A documented medical need for a walker, bilateral canes, or bilateral crutches; or
- An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity.

In proposed 114.04 *Systemic sclerosis (scleroderma*), 114.05 *Polymyositis and dermatomyositis,* and 114.09 *Inflammatory arthritis* for children, we would replace ''inability to ambulate effectively'' with the requirement of one of the following:

- A documented medical need for a walker, bilateral canes, or bilateral crutches; or
- An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity.

In proposed 14.04 *Systemic sclerosis (scleroderma),* 14.05 *Polymyositis and dermatomyositis,* and 14.09 *Inflammatory arthritis* for adults, we would replace ''inability to perform fine and gross movements effectively'' with ''inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.''

In proposed 114.04 *Systemic sclerosis (scleroderma),* 114.05 *Polymyositis and dermatomyositis,* and 114.09 *Inflammatory arthritis* for children, we would replace ''inability to perform fine and gross movements effectively'' with ''inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.''

In proposed 14.09 *Inflammatory arthritis* and 114.09 *Inflammatory arthritis,* we would replace ''major peripheral weight-bearing joints'' with ''major joints in a lower extremity(ies).'' In proposed 14.09 *Inflammatory arthritis* and 114.09 *Inflammatory arthritis,* we would replace ''major peripheral joints'' with ''major joints'' or ''major joints of an upper or lower extremity(ies),'' as appropriate for the affected extremity(-ies).

We propose to remove the first and second examples in § 416.926a(m) of this chapter, *Examples of impairments that functionally equal the listings.* The first example is ''[a]ny condition that is disabling at the time of onset, requiring continuing surgical management within 12 months after onset as a life-saving measure or for salvage or restoration of function, and such major function is not restored or is not expected to be restored within 12 months after onset of this condition.'' (See § 416.926a(m)(1) of this chapter.) We are removing this example because, at the time it was written, there were no specific criteria that considered the need for ongoing surgical management in the listings. The second example is ''[e]ffective ambulation possible only with obligatory bilateral upper limb assistance.'' (See § 416.926a(m)(2) of this chapter.) We are removing this example because several of the proposed childhood listings include a criterion considering ''. . . a documented medical need for a walker, bilateral canes, or bilateral crutches'' (that is, ''obligatory bilateral upper limb assistance.'') With the inclusion of the proposed childhood listings, it will no longer be necessary to have these examples in the regulations.

IX. Administrative Matters

What is our authority to make rules and set procedures for determining whether a person is disabled under our statutory definition?

The Social Security Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them.[10]

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?

[10] Sections 205(a), 702(a)(5), and 1631(d)(1).

• Would a different format make the rules easier to understand, *e.g.,* grouping and order of sections, use of headings, paragraphing?

Anticipated Economic Impact of the Proposed Rules

Financial Classification of SSA's Regulations

Based on criteria established by OMB Circular A–4 and Executive Order 13771, we classify this rule as a ''transfer rule.'' Transfer rules do not create or impose novel costs; rather, they regulate the transfer of monetary payments from one group to another without affecting the total resources available to society.

Under our Old-Age, Survivors, and Disability Insurance program (OASDI), SSA's regulations govern the transfer of benefits payments to qualified workers primarily from revenues collected from payroll taxes (FICA) and self-employment taxes (SECA). Under the Supplemental Security Income (SSI) program, funded by general tax revenues, SSA makes payments to individuals with limited income and resources who are aged, blind, or disabled.

This proposed rule establishes eligibility criteria for transferring disability payments to those persons who qualify for such payments based on the presence of a musculoskeletal body system disorder.

Anticipated Accounting Costs of These Proposed Rules

Anticipated Costs to Our Programs

For fiscal years (FY) 2018–2022, our Office of the Chief Actuary estimates that this proposed rule, once finalized, may result in a reduction of $57,000,000 to our OASDI program costs, and an increase of $11,000,000 to our SSI program costs. It is important to note that due to the roughly offsetting estimated effects of changes from allowance to denial and from denial to allowance, the true net effect for either program, OASDI or SSI, could potentially be either a small cost or a small saving.

Anticipated Administrative Costs to the Social Security Administration

In calculating whether the implementation of this proposed rule, once finalized, may result in administrative costs or savings to the agency, we examine two sources: (1) Work-years and (2) direct financial administrative costs.

We define work-years as a measure of the SSA employee work time a proposed rule will cost or save during implementation of its policies. We calculate one work-year as 2,080 hours of labor, which represents the amount of hours one SSA employee works per year based on a standard 40-hour workweek.

We estimate the direct financial administrative costs of a proposed rule by examining requirements stemming from new regulations, including systems start-up and maintenance costs, operational costs resulting from new workloads, and internal training costs for relevant agency staff and adjudicators. To assess savings resulting from a proposed rule, we examine Systems and operational workload changes.

Based on the above factors, our Office of Budget, Finance, and Management estimates that implementation of these proposed rules, upon finalization, will result in overall administrative savings for SSA of fewer than 15 work-years and less than $2 million annually for the period of FY 2018–2022.

When will we start to use these rules?

We will not use these rules until we evaluate public comments and publish final rules in the **Federal Register**. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of those relevant comments we received along with responses and an explanation of how we will apply the new rules.

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this notice of proposed rulemaking (NPRM) meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed it.

Regulatory Flexibility Act

We certify that this NPRM will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

These proposed rules do not create any new or affect any existing collections and, therefore, do not require OMB approval under the Paperwork Reduction Act.

X. References

We consulted the following references when we developed these proposed rules:

Alentado, V.J., Caldwell, S., Gould, H.P., Steinmetz, M.P., Benzel, E.C., & Mroz, T.E. (2017). Independent predictors of a clinically significant improvement after lumbar fusion surgery. *The Spine Journal, 17*(2), 236–243. *http://doi.org/10.1016/j.spinee.2016.09.011.*

Anatchkova, M.D., Saris-Baglama, R.N., Kozinski, M., & Bjorner, J.B. (2009). Development and preliminary testing of a computerized adaptive assessment of chronic pain. *The Journal of Pain, 10*(9), 932–943. *http://doi.org/10.1016/j.jpain.2009.03.007.*

Arosarena, O.A. (2007). Cleft lip and palate. *Otolaryngologic Clinics of North America, 40*(1), 27–60. *http://doi.org/10.1016/j.otc.2006.10.011.*

Baber, Z. & Erdek M.A. (2016). Failed back surgery syndrome: Current perspectives. *Journal of Pain Research, 9,* 979–987. *http://doi.org/10.2147/JPR.S92776.*

Bateni, H. & Maki, B.E. (2005). Assistive devices for balance and mobility: Benefits, demands, and adverse consequences. *Archives of Physical Medicine and Rehabilitation. 86,* 134–145. *http://doi.org/10.1016/j.apmr.2004.04.023.*

Belthur, M.V., Birchansky, S.B., Verdugo, A.A., Mason, E.O., Hulten, K.G., Kaplan, S.L., . . . Weinberg, J. (2012). Pathologic Fractures in children with acute Staphylococcus aureus osteomyelitis. *The Journal of Bone and Joint Surgery-American Volume, 94*(1), 34–42. *http://doi.org/10.2106/JBJS.J.01915.*

Bernard, B.P. (Ed.). (1997). *Musculoskeletal disorders and workplace factors—a critical review of epidemiologic evidence for work-related musculoskeletal disorders of the neck, upper extremity, and low back* (Pub. no. 97–141). Cincinnati, OH: National Institute for Occupational Safety and Health. Retrieved from: *https://www.cdc.gov/niosh/docs/97-141/pdfs/97-141.pdf.*

Berger, E. (2000). Late postoperative results in 1000 work related lumbar spine conditions. *Surgical Neurology, 54*(2), 101–108. *http://doi.org/10.1016/S0090-3019(00)00283-4.*

Bokov, A., Istrelov, A.I., Skorodumov, A.S., Aleynik, A., Simonov, A., & Mlyavykh, S. (2011). An analysis of reasons for failed back surgery syndrome and partial results after different types of surgical lumbar nerve root decompression. *Pain Physician Journal, 14,* 545–557. PMID:22086096.

Bostelmann, R., Bostelmann, T., Nasaca, A., Steiger, H.J., Zaucke, F., & Schleich, C. (2017). Biochemical validity of imaging techniques (X-ray, MRI, and dGEMRIC) in degenerative disc disease of the human cervical spine—an in vivo study. *The Spine Journal, 17*(2), 196–202. *http://doi.org/10.1016/j.spinee.2016.08.031.*

Brandt, K. (2001). *An atlas of osteoarthritis.* Boca Raton, FL: CRC Press.

Brown, D.E., & Neumann, R.D. (2004). *Orthopedic Secrets* (3rd ed.). New York: Elsevier Saunders.

Canale, S.T. (Ed). (2003). *Campbell's Operative Orthopedics* (10th ed.). St. Louis, MO: Mosby.

Campbell, A., Costello, B.J., & Ruiz, R.L. (2010). Cleft lip and palate surgery: An update of clinical outcomes for primary repair. *Oral and Maxillofacial Surgery Clinics of North America, 22*(1), 43–58. *http://doi.org/10.1016/j.coms.2009.11.003.*

Chan, C., & Peng, P. (2011). Failed back s syndrome. *Pain Medicine, 12*(4), 577–606. *http://doi.org/10.1111/j.1526-4637.2011.01089.x.*

Crawford, C.H., Glassman, S.D., Mummaneni, P.V., Knightly, J.J., & Asher, A.L. (2016). Back pain improvement after decompression without fusion or stabilization in patients with lumbar spinal stenosis and clinically significant preoperative back pain. *Journal of Neurosurgery: Spine, 25*(5), 596–601. *http://doi.org/10.3171/2016.3.spine151468.*

de Graaf, I., Prak, A., Bierma-Zeinstra, S., Thomas, S., Peul, W., & Koes, B. (2006). Diagnosis of lumbar spinal stenosis. *Spine, 31*(10), 1168–1176. *http://doi.org/10.1097/01.brs.0000216463.32136.7b.*

Dionne, C.E., Bourbonnais, R., Fremont, P., Rossignol, M., Stock, S.R., & Larocque, I. (2005). A clinical return-to-work rule for patients with back pain. *Canadian Medical Association Journal, 172*(12), 1559–1567. *http://doi.org/10.1503/cmaj.1041159.*

Djurasovic, M., Bratcher, K.R., Glassman, S.D., Dimar, J.R., & Carreon, L.Y. (2008). The effect of obesity on clinical outcomes after lumbar fusion. *Spine, 33*(16), 1789–1792. *http://doi.org/10.1097/BRS.0b013e31817b8f6f.*

Doherty, G.M., & Way, L.W. (2006). *Current surgical diagnosis & treatment* (12th ed.). New York, NY: McGraw-Hill.

Eliasberg, C.D., Kelly, M.P., Ajiboye, R.M., & Soohoo, N.F. (2016). Complications and rates of subsequent lumbar surgery following lumbar total disc arthroplasty and lumbar fusion. *Spine, 41*(2), 173–181. *http://doi.org/10.1097/BRS.0000000000001180.*

Fanuele, J.C., Abdu, W.A., Hanscom, B., & Weinstein, J.N. (2002). Association between obesity and functional status in patients with spine disease. *Spine, 27*(3), 306–312. *http://doi.org/10.1097/00007632-200202010-00021.*

Faruqui, S.R., & Jaeblon, T. (2010). Ambulatory Assistive Devices in Orthopaedics: Uses and Modifications. *Journal of the American Academy of Orthopaedic Surgeons. 18*(1), 41–50. *http://doi.org/10.5435/00124635-201001000-00006.*

Fritz, J.M., Delitto, A., Welch, W.C., & Erhard, R.E. (1998). Lumbar spinal stenosis: Review of current concepts in evaluation, management, and outcome measurements. *Archives of Physical Medicine and Rehabilitation, 79*(6), 700–708. *http://doi.org/10.1016/S0003-9993(98)90048-X.*

Gettys, F.K., Jackson, J.B., & Frick, S.L. (2011). Obesity in pediatric orthopaedics. *Orthopedic Clinics of North America, 42*(1), 95–105. *http://doi.org/10.1016/j.ocl.2010.08.005.*

Haase, S.C. (2013). Treatment of Pathologic Fractures. *Hand Clinics, 29*(4), 579–584. *http://doi.org/10.1016/j.hcl.2013.08.010.*

Hadler, N.M. (2005). *Occupational Musculoskeletal Disorders* (3rd ed.). Philadelphia, PA: Lippincott, Williams & Wilkins.

Haig, A.J., Geisser, M.E., Tong, H.C., Yamakawa, K.S.J., Quint, D.J., Hoff, J.T., . . . Phalke, V.V. (2007). Electromyographic and magnetic resonance imaging to predict lumbar stenosis, low-back pain, and no back symptoms. *Journal of Bone and Joint Surgery, 89*(2), 358–366. *http://doi.org/10.2106/00004623-200702000-00018.*

Haig, A.J., Tong, H.C., Yamakawa, K.S., Parres, C., Quint, D.J., Chiodo, A., . . . Geisser, M.E. (2006). Predictors of pain and function in persons with spinal stenosis, low back pain, and no back pain. *Spine, 31*(25), 2950–2957. *http://doi.org/10.1097/01.brs.0000247791.97032.1e.*

Haig, A.J., Tong, H.C., Yamakawa, K.S., Quint, D.J., Hoff, J.T., Choido, A., . . . Parres, C.M. (2006). Spinal stenosis, back pain, or no symptoms at all? A masked study comparing radiologic and electrodiagnostic diagnoses to the clinical impression. *Archives of Physical Medicine and Rehabilitation, 87*(7), 897–903. *http://doi.org/10.1016/j.apmr.2006.03.016.*

Hutson, M. & Ward, A. (Eds.). (2016). *Oxford Textbook of Musculoskeletal Medicine* (2nd ed.). Oxford, UK: Oxford University Press.

Institute of Medicine, Committee on Advancing Pain Research, Care, and Education. (2011). *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington, DC: The National Academies Press.

Jönsson, B., Annertz, M., Sjöberg, C., & Strömqvist, B. (1997). A prospective and consecutive study of surgically treated lumbar spinal stenosis. Part I: Clinical features related to radiographic findings. *Spine, 22*(24), 2932–2937. *http://doi.org/10.1097/00007632-199712150-00016.*

Jönsson, B., Annertz, M., Sjöberg, C., & Strömqvist, B. (1997). A prospective and consecutive study of surgically treated lumbar spinal stenosis. Part II: Five-year follow-up by an independent observer. *Spine, 22*(24), 2938–2944. *http://doi.org/10.1097/00007632-199712150-00017.*

Karmarkar, A.M., Collins, D.M., Wichman, T., Franklin, A., Fitzgerald, S.G., Dicianno, B.E., . . . Cooper, R.A. (2009). Prosthesis and wheelchair use in veterans with lower-limb amputation. *Journal of Rehabilitation Research & Development, 46*(5), 567–576. *http://doi.org/10.1682/JRRD.2008.08.0102.*

Kim, Y., Morshed, S., Joseph, T., Bozic, K., Ries, M., & Ries, M.D. (2006). Clinical impact of obesity on stability following revision total hip arthroplasty. *Clinical Orthopaedics & Related Research, 453,* 142–146. *http://doi.org/10.1097/01.blo.0000238874.09390.a1.*

Kliegman, R.M., Stanton, B.F., Schor, N.F., St. Geme III, J.W., Behrman, R.E., (Eds.). (2016). *Nelson Textbook of Pediatrics.* (20th ed., Vol. 1). Philadelphia, PA: Elsevier.

Lohman, C.M., Tallroth, K., Kettunen, J.A., & Lindgren, K.A. (2006). Comparisons of radiologic signs and clinical symptoms of spinal stenosis. *Spine, 31*(16), 1834–1840. *http://doi.org/10.1097/01.brs.0000227370.65573.ac.*

Longo, D.L., Fauci, A.S., Kasper, D.L., Hauser, S.L., Jameson, J.L., & Loscalzo, J.L. (2011). *Harrison's Principles of Internal Medicine* (18th ed.). New York, NY: McGraw-Hill Medical.

Mannion, A.F., Brox, J.I., & Fairbank, J.C.T. (2013). Comparison of spinal fusion and nonoperative treatment in patients with chronic low back pain: Long-term follow-up of three randomized controlled trials. *The Spine Journal, 13*(11), 1438–1448. *http://doi.org/10.1016/j.spinee.2013.06.101.*

Martel, M.O., Finan, P.H., Dolman, A.J., Subramanian, S., Edwards, R.R., Wasan, A.D., & Jamison, R.N. (2015). Self-reports of medication side effects and pain-related activity interference in patients with chronic pain: A longitudinal cohort study. *Pain. 156*(6), 1092–1100. *http://doi.org/10.1097/j.pain.0000000000000154.*

Martindale, J., Sulka, R. & Goodacre, J. (2015). The impact of ankylosing spondylitis/Axial spondyloarthritis on work productivity. *Best Practice & Research Clinical Rheumatology, 29*(3), 512–523. *http://doi.org/10.1016/j.berh.2015.04.002.*

Mattos, C.B., Binitie, O., & Dormans, J.P. (2012). Pathological fractures in children. *Bone and Joint Research, 1*(10), 272–280. *http://doi.org/10.1302/2046-3758.110.2000120.*

Ökmen, K., & Ökmen, B.M. (2017). The efficacy of interlaminar epidural steroid administration in multilevel intervertebral disc disease with chronic low back pain: A randomized, blinded, prospective study. *The Spine Journal, 17*(2), 168–174. *http://doi.org/10.1016/j.spinee.2016.08.024.*

Onyekwelu, I., Glassman, S.D., Asher, A.L., Shaffrey, C.I., Mummaneni, P.V., & Carreon, L.Y. (2017). Impact of obesity on complications and outcomes: A comparison of fusion and nonfusion lumbar spine surgery. *Journal of Neurosurgery: Spine. 26*(2), 158–162. *http://doi.org/10.3171/2016.7.SPINE16448.*

Puolakka, K., Ylinen, J., Neva, M.H., Kautiainen, H., & Häkkinen, A. (2008). Risk factors for back pain-related loss of working time after surgery for lumbar disc herniation: A 5-year follow-up study. *European Spine Journal, 17*(3), 386–392. *http://doi.org/10.1007/s00586-007-0552-2.*

Reed, P. (2005). *The Medical Disability Advisor* (5th ed.). Westminster, CO: Reed Group, Ltd.

Rondinelli, R.D., Genovese, E., Katz, R.T., Mayer, T.G., Mueller, K., Ranavaya, M. (Eds.). (2007). *Guides to the Evaluation of Permanent Impairment* (6th ed.). Chicago, IL: American Medical Association.

Shin, E.K., Kim, C.H., Chung, C.K., Choi, Y., Yim, D., Jung, W., . . . Kim, S.M. (2017). Sagittal imbalance in patients with lumbar spinal stenosis and outcomes after simple decompression surgery. *The Spine Journal, 17*(2), 175–182. *http://doi.org/10.1016/j.spinee.2016.08.023.*

Sigmundsson, F.G. (2014). Determinants of outcome in lumbar spinal stenosis surgery. *Acta Orthopaedica, 85*(Sup357), 1–45. *http://doi.org/10.3109/17453674.2014.976807.*

Skinner, H.B., & McMahon, P.J. (2013). *Current Diagnosis & Treatment in Orthopedics* (5th ed.). New York, NY: McGraw-Hill Education.

Spivak, J.M. (1998). Current concepts review: Degenerative lumbar spinal stenosis. *Journal of Bone and Joint Surgery, 80*(7), 1053–1066. *http://doi.org/10.2106/00004623-199807000-00015.*

Taylor, M.E. (1989). Return to work following back surgery: A review. *American Journal of Industrial Medicine, 16,* 79–88. *http://doi.org/10.1002/ajim.4700160109.*

Telfeian, A.E., Reiter, T., Durham, S.R., & Marcotte, P. (2002). Spine surgery in morbidly obese patients. *Journal of Neurosurgery: Spine, 97*(1), 20–24. *http://doi.org/10.3171/spi.2002.97.1.0020.*

Thomason, T., Burton, J.F., & Hyatt, D. (Eds.). (1998). *New approaches to disability in the workplace.* New York: Cornell University Press.

Urquhart, D.M., Berry, P., Wluka, A.E., Strauss, B.J., Wang, Y., Proietto, J., . . . Cicuttini, F.M. (2011). 2011 young investigator award winner: Increased fat mass is associated with high levels of low back pain intensity and disability. *Spine, 36*(16), 1320–1325. *http://doi.org/10.1097/BRS.0b013e3181f9fb66.*

Vaidya, R., Carp, J., Bartol, S., Ouellette, N., Lee, S., & Sethi, A. (2009). Lumbar spine fusion in obese and morbidly obese patients. *Spine, 34*(5), 495–500. *http://doi.org/10.1097/BRS.0b013e318198c5f2.*

Varni, J.W., Stucky, B.D., Thissen, D., Dewitt, E.M., Irwin, D.E., Lai, J.S., . . . DeWalt, D.A. (2010). PROMIS pediatric pain interference scale: An item response theory analysis of the pediatric pain item bank. *The Journal of Pain, 11*(11), 1109–1119. *http://doi.org/10.1016/j.jpain.2010.02.005.*

Vendrig, A.A. (1999). Prognostic factors and treatment-related changes associated with return to work in the multimodal treatment of chronic back pain. *Journal of Behavioral Medicine, 22*(3), 217–232. *http://doi.org/10.1023/A:1018716406511.*

Wang, Y., Hart, D.L., Wernecke, M., Stratford, P.W., & Mioduski, J.E. (2010). Clinical interpretation of outcome measures generated from a lumbar computerized adaptive test. *Physical Therapy, 90*(9), 1323–1335. *http://doi.org/10.2522/ptj.20090371.*

Weinstein, S.L., & Buckwalter, J.A. (Eds.). (2005). *Turek's orthopaedics: Principles and their application* (6th ed.). Philadelphia, PA: Lippincott Williams and Wilkins.

Weiser, P. (2012). Approach to the patient with noninflammatory musculoskeletal pain. *Pediatric Clinics of North America, 59*(2), 471–492. *http://doi.org/10.1016/j.pcl.2012.03.012.*

Yong, V. (2010) Mobility limitations. In: JH Stone, M Blouin, (Eds). International encyclopedia of rehabilitation. *Center for International Rehabilitation Research Information and Exchange. http://cirrie.buffalo.edu/encyclopedia/en/article/259/.*

Young, A.E., & Murphy, G.C. (2009). Employment status after spinal cord injury (1992–2005): A review with implications for interpretation, evaluation, further research, and clinical practice. *International Journal of Rehabilitation Research, 32*(1), 1–11. *http://doi.org/10.1097/MRR.0b013e32831c8b19.*

We included these references in the rulemaking record for these proposed rules and will make them available for inspection by interested individuals who make arrangements with the contact person identified above.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security–Disability Insurance; 96.002, Social Security–Retirement Insurance; 96.004, Social Security–Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects

20 CFR Part 404

Administrative practice and procedure; Blind, Disability benefits; Old-Age, survivors, and disability insurance; Reporting and recordkeeping requirements; Social Security.

20 CFR Part 416

Administrative practice and procedure, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Nancy A. Berryhill,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend 20 CFR, chapter III, part 404, subpart P as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 as follows:

■ a. Revise item 2 of the introductory text before part A;

■ b. Amend part A by revising the body system name for section 1.00 in the table of contents;

■ c. Revise section 1.00 of part A;

■ d. Revise the second sentence of paragraph 4.00G4b of part A;

■ e. Redesignate current 14.00C2 through 14.00C12 of part A as follows:

Old section	New section
14.00C2	14.00C3
14.00C3	14.00C4
14.00C4	14.00C6
14.00C5	14.00C7
14.00C6	14.00C8
14.00C7	14.00C9
14.00C8	14.00C10
14.00C9	14.00C11
14.00C10	14.00C12
14.00C11	14.00C13
14.00C12	14.00C14

■ f. Add new paragraphs 14.00C2 and 14.00C5 to part A;

■ g. Revise 14.00C8 through 14.00C10;

■ h. Revise the first sentence of paragraph 14.00D4c(i) of part A;

■ i. Revise the second and third sentences of paragraph 14.00D6a of part A;

■ j. Revise paragraph 14.00D6e(i) and the first sentence of 14.00D6e(ii) of part A;

■ k. Revise 14.04B, 14.04C2, and 14.05A of part A;

■ l. Revise 14.09A and the first sentence of 14.09B of part A;

■ m. Amend part B by revising the body system name for section 101.00 in the table of contents;

■ n. Revise section 101.00 of part B;

■ o. Revise the second sentence of paragraph 104.00F9b of part B;

■ p. Redesignate current 114.00C2 through 114.00C12 of part B as follows:

Old section	New section
114.00C2	114.00C3
114.00C3	114.00C4
114.00C4	114.00C6
114.00C5	114.00C7
114.00C6	114.00C8
114.00C7	114.00C9
114.00C8	114.00C10
114.00C9	114.00C11
114.00C10	114.00C12
114.00C11	114.00C13
114.00C12	114.00C14

■ q. Add new paragraphs 114.00C2 and 114.00C5 to part B;

■ r. Revise 114.00C8 through 114.00C10;
■ s. Revise the first sentence of paragraph 114.00D4c(ii) of part B;
■ t. Revise the second and third sentences of paragraph 114.00D6a of part B;
■ u. Revise paragraph 114.00D6e(i) and the first sentence of 114.00D6e(ii) of part B;
■ v. Revise listings 114.04B, 114.04C2, and 114.05A of part B; and
■ w. Revise 114.09A and the heading of 114.09B of part B.

The revisions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

2. Musculoskeletal Disorders (1.00 and 101.00): [THIS EXPIRES 5 YEARS FROM THE EFFECTIVE DATE OF THE FINAL RULES].

* * * * *

Part A

* * * * *

1.00 Musculoskeletal Disorders.

* * * * *

1.00 Musculoskeletal Disorders

A. *Which disorders do we evaluate under these listings?*

1. We evaluate disorders of the skeletal spine (vertebral column) or of the upper or lower extremities that affect musculoskeletal functioning in the musculoskeletal body system listings. We use the term ''skeletal'' when we are referring to the structure of the bony skeleton. The skeletal spine refers to the bony structures, ligaments, and discs making up the spine. We refer to the ''skeletal'' spine in some musculoskeletal listings to differentiate it from the neurological spine (see 1.00B1). Disorders may be congenital or acquired, and may include deformities, amputations, or other musculoskeletal abnormalities. These disorders may involve the bones or major joints; or the tendons, ligaments, muscles, or other soft tissues.

2. We also evaluate soft tissue abnormalities or injuries (including burns) that are under continuing surgical management (see 1.00L1). The abnormalities or injuries may affect any part of the body, including the face and skull.

B. *Which related disorders do we evaluate under other listings?*

1. We evaluate a disorder or injury of the skeletal spine that results in damage to, and neurological dysfunction of, the spinal cord and its associated nerves (for example, paraplegia or quadriplegia) under the criteria in 11.00 *Neurological Disorders.*

2. We evaluate inflammatory arthritis (for example, rheumatoid arthritis) under the criteria in 14.00 *Immune System Disorders.*

3. We evaluate curvatures of the skeletal spine under these musculoskeletal disorders listings and other listings as appropriate for the affected body system. Curvatures of the skeletal spine that affect musculoskeletal functioning are evaluated under 1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s).* If a curvature of the skeletal spine is under continuing surgical management, we can evaluate it for medical equivalence to 1.21 *Soft tissue injury or abnormality under continuing surgical management.* Curvatures of the skeletal spine may also adversely affect functioning in body systems other than the musculoskeletal system. For example, the curvature may interfere with your ability to breathe (see 3.00 *Respiratory Disorders*); there may be impaired myocardial function (see 4.00 *Cardiovascular System*); or there may be disfigurement resulting in social withdrawal or depression (see 12.00 *Mental Disorders*).

4. We evaluate non-healing or pathological fractures due to cancer, whether it is a primary site or metastases, under the criteria in 13.00 *Cancer (Malignant Neoplastic Diseases).*

5. We evaluate the leg pain associated with peripheral vascular claudication, as well as diabetic foot ulcers, under the criteria in 4.00 *Cardiovascular System.*

6. We evaluate burns that do not require continuing surgical management under the criteria in 8.00 *Skin Disorders.*

C. *What evidence do we need to evaluate your musculoskeletal disorder under these listings?*

1. *General.* To establish the presence of a musculoskeletal disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source who has examined you for the disorder. To assess the severity and duration of your disorder, we evaluate evidence from both medical and nonmedical sources who can describe how you function. If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 1.00P *How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment*? We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 404.1502, 404.1512, 404.1513, 404.1513a, 404.1520b, 416.902, 416.912, 416.913, 416.913a, and 416.920b of this chapter. For our rules on evidence about your symptoms, see §§ 404.1529 and 416.929 of this chapter.

2. *Physical examination report(s).* In the report(s) of your physical examination, we need a detailed description of the orthopedic, neurologic, or other objective clinical findings appropriate to your specific musculoskeletal disorder. We require objective clinical findings from the medical source's direct observations during your physical examination, not simply his or her report of your statements about your symptoms and limitations. When the medical source reports that a clinical test sign(s) is positive, unless we have evidence to the contrary, we will assume that he or she performed the test properly. For instance, we will assume a straight-leg raising test was conducted properly, *i.e.,* in a sitting and supine position, even if the medical source does not specify the positions in which the test was performed. In the absence of evidence to the contrary, we will accept the medical source's interpretation of the test. If you use an assistive device (see 1.00C6), the report must support the medical need for the device. If reduction in muscle strength is a factor, we require medical documentation of measurement of the strength of the muscle(s) in question, generally based on a grading system of 0 to 5. Zero (0) indicates complete loss of strength and 5 indicates maximum strength, consistent with Table 1 below. The documentation should also include measurements of grip and pinch strength, if there is evidence of involvement of one or both hands.

TABLE 1

Grading Scale of Muscle Function: 0 to 5

0	None	No visible or palpable contraction.
1	Trace	Visible or palpable contraction with no motion.
2	Poor	Active range of motion (ROM) with gravity eliminated.
3	Fair	Active ROM against gravity only, without resistance.
4	Good	Active ROM against gravity, moderate resistance.
5	Normal	Active ROM against gravity, maximum resistance.

3. *Laboratory findings: Imaging and other diagnostic tests*

a. Imaging refers to medical imaging techniques, such as x-ray, computed tomography (CT), magnetic resonance imaging (MRI), and radionuclide scanning. For the purpose of these listings, the imaging technique(s) must be consistent with the generally accepted standards of medical knowledge and clinical practice.

b. Findings on imaging must have lasted, or must be expected to last, for a continuous period of at least 12 months.

c. Imaging and other diagnostic tests can provide evidence of physical abnormalities; however, they may correlate poorly with

your symptoms, including pain, or with your musculoskeletal functioning. Accordingly, we cannot use such tests as a substitute for physical examination findings about your ability to function, nor can we infer severity or functional limitations based solely on such tests.

d. For our policies about when we will purchase imaging and other diagnostic tests, see §§ 404.1519k, 404.1519m, 416.919k, and 416.919m of this chapter.

4. *Operative reports.* If you have had a surgical procedure(s), we need either the operative reports, including details of the findings at surgery and information about any medical complications that may have occurred, or confirmatory evidence of the surgical procedure(s) from a medical source (for example, detailed follow-up reports or notations in the medical records concerning your past medical history).

5. *Effects of treatment*

a. *General.* Treatments for musculoskeletal disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your musculoskeletal disorder, and on your musculoskeletal functioning.

b. *Response to treatment.* To evaluate your musculoskeletal functioning in response to treatment, we need specific information related to your impairment, including the following: A description of your medications, including frequency of administration; the type and frequency of therapy you receive; and a description of your response to treatment and any complications you experience related to your impairment. The effects of treatment may be temporary or long-term. We need information over a sufficient period to determine the effect of treatment on your current musculoskeletal functioning and to permit reasonable projections about your future functioning. In some cases, we will need additional evidence to make an assessment about your response to treatment. Depending upon the timing of this treatment in relation to the alleged onset date of disability, we may need to defer evaluation of the impairment for a period of up to 3 months from the date treatment began to permit consideration of treatment effects, unless we can make a determination or decision using the evidence we have.

6. *Assistive devices*

a. *General.* An assistive device, for the purposes of these listings, is any device that is used to improve stability, dexterity, or mobility. An assistive device can be worn (see 1.00C6b and c), or hand-held (see 1.00C6d). If you use any type of assistive device(s), we need evidence from a medical source regarding the documented medical need for the device(s). When we use the term ''documented medical need,'' we mean that there is evidence from a medical source(s) in the medical record that supports your need for an assistive device (see §§ 404.1513 and 416.913 of this chapter). The evidence must include documentation from a medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device(s), and the circumstances for which you need it. The evidence does not have to include a specific prescription for the device(s).

b. *Prosthesis(es).* A prosthesis is a wearable device, such as an artificial limb, that takes the place of an absent body part. We need evidence from a medical source documenting your ability to walk, or to perform fine and gross movements (see 1.00E3), with the prosthesis(es) in place. When amputation(s) involves a lower extremity or extremities, it is not necessary to evaluate your ability to walk without the prosthesis(es) in place. If you cannot use your prosthesis(es) due to complications affecting your residual limb(s), we need documentation from a medical source regarding the condition of your residual limb(s) and the medical basis for your inability to use the prosthesis(es).

c. *Orthosis(es).* An orthosis is a wearable device that prevents or corrects a dysfunction or deformity by aligning or supporting the affected body part. An orthosis may also be referred to as a ''brace.'' If you have an orthosis(es), we need evidence from a medical source documenting your ability to walk, or to perform fine and gross movements, with the orthosis(es) in place. If you cannot use your orthosis(es), we need evidence from a medical source documenting the medical basis for your inability to use the device(s).

d. *Hand-held assistive devices.* Hand-held assistive devices include canes, crutches, or walkers, and are carried in your hand(s) to support or aid you in walking. When you require a one-handed assistive device for ambulation, such as a cane or single crutch, and your other upper extremity has limitations preventing its use for fine or gross movement(s) (see 1.00E3), the need for the assistive device limits the use of both upper extremities. If you use a hand-held assistive device, we need evidence from a medical source documenting your need for the device(s) and describing how you walk with the device(s).

7. *Longitudinal evidence*

a. We generally need a longitudinal medical record to assess the duration of your musculoskeletal disorder, because symptoms, signs, and laboratory findings related to most musculoskeletal disorders may wax and wane, may improve over time, or may respond to treatment. By providing evidence over an extended period, the medical record will show whether your musculoskeletal functioning is improving, worsening, or unchanging.

b. For 1.19 *Pathologic fractures due to any cause* and 1.21 *Soft tissue injury or abnormality under continuing surgical management,* the required 12-month duration period is stated in the listing itself. For 1.20A (amputation of both upper extremities) or 1.20B (hemipelvectomy or hip disarticulation), we presume satisfaction of the duration requirement.

c. For all listings not referenced in 1.00C7b above, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. When we use the term ''close proximity of time,'' we mean that all of the relevant criteria have to appear in the medical record within a period not to exceed 4 months of one another. When the criterion in question is imaging, we mean those findings on imaging that we could reasonably expect to have been present at the date of impairment or date of onset. To meet a listing that uses the word ''and'' or ''AND'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

8. *Surgical treatment*

For some musculoskeletal disorders, a medical source may recommend surgery. If you have not yet had the recommended surgery, we will not deny your claim based on an assumption that surgery will resolve or improve your disorder. We will assess each case on an individual basis. Depending on your response to treatment, or depending on your medical sources' treatment plans, we may defer our findings regarding the effect of surgical intervention until a sufficient period has passed to permit proper consideration or judgment about your future functioning. See 1.00C5b *Response to treatment.*

D. *How do we consider symptoms, including pain, under these listings?*

1. Individuals with musculoskeletal disorders may experience pain or other symptoms; however, statements alone about your pain or other symptoms cannot establish that you are disabled. Further, an alleged or reported increase in the intensity of a symptom, such as pain, no matter how severe, cannot be substituted for a medical sign or diagnostic finding present in the listing criteria. Pain is included as just one consideration in paragraph A in listings 1.15, 1.16, and 1.18, but is not required to satisfy the criteria in these listings. Examples of other findings that will satisfy the criteria in paragraph A include muscle fatigue, nonradicular distribution of sensory loss in one or both extremities, and joint stiffness.

2. To consider your pain, we require objective medical evidence from an acceptable medical source showing the existence of a medically determinable impairment(s) (MDI) that could reasonably be expected to produce the pain. When your musculoskeletal MDI could reasonably be expected to produce the pain or other symptoms alleged, we consider all your symptoms, including pain, and the extent to which your symptoms can reasonably be accepted as consistent with all of the objective medical evidence, including medical signs and laboratory or diagnostic findings. See §§ 404.1529 and 416.929 of this chapter for information on how we evaluate pain or other symptoms related to a musculoskeletal impairment.

E. *How do we use the functional criteria under these listings?*

1. *General.* We will determine that your musculoskeletal disorder meets a listing if it satisfies the medical criteria; includes at least one of the functional criteria, if included in the listing; and satisfies the 12-month duration requirement. We will use the relevant evidence that we have to evaluate

your musculoskeletal functioning with respect to the work environment rather than the home environment. For example, an ability to walk independently at home without an assistive device does not, in and of itself, indicate an ability to walk without an assistive device in a work environment.

2. *Functional criteria.* The functional criteria are based on impairment-related physical limitations in your ability to use both upper extremities, one or both lower extremities, or a combination of one upper and one lower extremity. A musculoskeletal disorder satisfies the functional criteria of a listing when the medical documentation shows the presence of at least one of the impairment-related limitations cited in the listing. The required impairment-related physical limitation of musculoskeletal functioning must have lasted, or be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

a. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d);

b. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E3), and a documented medical need (see 1.00C6a) for a one-handed assistive device (see 1.00C6d) that requires the use of your other upper extremity;

c. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E3).

3. *Fine and gross movements.* Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional abilities such as lifting, carrying, pushing, and pulling. Examples of inability to perform fine and gross movements include, but are not limited to, the inability to take care of personal hygiene, the inability to sort and handle papers or files, and the inability to place files in a file cabinet at or above waist level.

4. *When we do not use the functional criteria.* We do not use the functional criteria to evaluate amputation of both upper extremities under 1.20A, hemipelvectomy or hip disarticulation under 1.20B, and soft tissue injuries or abnormalities under continuing surgical management under 1.21.

F. *What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (1.15)?*

1. *General.* We consider musculoskeletal disorders such as herniated nucleus pulposus, spinal osteoarthritis (spondylosis), vertebral slippage (spondylolisthesis), degenerative disc disease, facet arthritis, and vertebral fracture or dislocation. Spinal disorders may cause cervical or lumbar spine dysfunction when abnormalities of the skeletal spine compromise nerve roots of the cervical spine, a nerve root of the lumbar spine, or a nerve root of both cervical and lumbar spines.

2. *Compromise of a nerve root(s).* Compromise of a nerve root(s), sometimes referred to as ''nerve root impingement,'' is a term used when a physical object is seen pushing on the nerve root in an imaging study or during surgery. Objects such as tumors, herniated discs, foreign bodies, or arthritic spurs may cause compromise of a nerve root. It can occur when a musculoskeletal disorder produces irritation, inflammation, or compression of the nerve root(s) as it exits the skeletal spine between the vertebrae. Related symptoms must be associated with, or follow the path of, the specific nerve root(s), thereby presenting a neuro-anatomic (usually referred to as ''radicular'') distribution of symptoms and signs, including pain, paresthesia (for example, burning, prickling, or tingling), sensory loss, and usually muscle weakness specific to the affected nerve root(s).

a. *Compromise of unilateral nerve root of the cervical spine.* Compromise of a nerve root as it exits the cervical spine between the vertebrae may affect the functioning of the associated upper extremity. The clinical examination reproduces the related symptoms based on radicular signs and clinical tests (for example, a positive Spurling's test) appropriate to the specific cervical nerve root.

b. *Compromise of bilateral nerve roots of the cervical spine.* Although uncommon, if compromise of a nerve root occurs on both sides of the cervical spinal column, functioning of both upper extremities may be limited.

c. *Compromise of a nerve root(s) of the lumbar spine.* Compromise of a nerve root as it exits the lumbar spine between the vertebrae may limit the functioning of the associated lower extremity. The clinical examination reproduces the related symptoms based on radicular signs and clinical tests. When a nerve root of the lumbar spine is compromised, we require a positive straight-leg raising test (also known as a Lasegue test) in both supine and sitting positions appropriate to the specific lumbar nerve root that is compromised. (See 1.00C2 for guidance on interpreting information from a physical examination report.)

G. *What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (1.16)?*

1. We consider the limiting effects of pain, sensory changes, and muscle weakness caused by compromise of the cauda equina due to lumbar spinal stenosis. The cauda equina is a bundle of nerve roots that descends from the lower part of the spinal cord. Lumbar spinal stenosis can compress the nerves of the cauda equina, causing sensory changes and muscle weakness that may affect your ability to stand or walk. Pain related to compromise of the cauda equina is ''nonradicular,'' because it is not typically associated with a specific nerve root (as is radicular pain in the cervical or lumbar spine).

2. Compromise of the cauda equina due to spinal stenosis can affect your ability to walk because of neurogenic claudication (also known as pseudoclaudication), a disorder usually causing non-radicular pain that starts in the low back and radiates bilaterally (or less commonly, unilaterally) into the buttocks and lower extremities (or extremity). Extension of the lumbar spine, as when walking or merely standing, provokes the pain of neurogenic claudication. It is relieved by forward flexion of the lumbar spine or by sitting. In contrast, the leg pain associated with peripheral vascular claudication results from inadequate arterial blood flow to a lower extremity. It occurs repeatedly and consistently when a person walks a certain distance and is relieved when the person rests.

H. *What do we consider when we evaluate reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (1.17)?*

1. We consider reconstructive surgery or surgical arthrodesis when an acceptable medical source(s) documents the surgical procedure(s) and associated medical treatments to restore function of the affected body part(s). The reconstructive surgery may be a single event or it may be a series of procedures directed toward the salvage or restoration of functional use of the affected joint.

2. *Major weight-bearing joints.* The major weight-bearing joints are the hip, knee, and ankle-foot. The ankle and foot are considered together as one major joint.

3. *Surgical arthrodesis.* Surgical arthrodesis is the artificial fusion of the bones that form a joint, essentially eliminating the joint.

I. *What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?*

1. *General.* We consider musculoskeletal disorders that produce anatomical abnormalities of major joints of the extremities, resulting in functional abnormalities in the upper or lower extremities (for example, osteoarthritis and chronic infections of bones and joints, surgical arthrodesis of a joint). Major joint of an upper extremity refers to the shoulder, elbow, and wrist-hand. We consider the wrist and hand together as one major joint. Major joint of a lower extremity refers to the hip, knee, and ankle-foot. We consider the ankle and hindfoot together as one major joint, because it is necessary for walking. Abnormalities affecting the joints may include ligamentous laxity or rupture, soft tissue contracture, or tendon rupture, and can cause muscle weakness of the affected body part.

2. *How do we define abnormality in the extremities?* An anatomical abnormality in any extremity(ies) is one that is readily observable by a medical source during a physical examination (for example, subluxation or contracture), or is present on imaging (for example, ankylosis, bony destruction, joint space narrowing, or deformity). A functional abnormality is abnormal motion or instability of the affected part(s), including limitation of motion, excessive motion (hypermobility), movement outside the normal plane of motion for the joint (for example, lateral deviation), or fixation of the affected parts.

J. *What do we consider when we evaluate pathologic fractures due to any cause (1.19)?*

We consider pathologic fractures of the bones in the skeletal spine, extremities, or other parts of the skeletal system. Pathologic fractures result from disorders that weaken the bones, making them vulnerable to breakage. For non-healing or complex traumatic fractures without accompanying pathology, see 1.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones* or 1.23 *Non-healing or complex fracture of an upper extremity.* Pathologic fractures may occur with osteoporosis, osteogenesis imperfecta or any other skeletal dysplasias, side effects of medications, and disorders of the endocrine or other body systems. They must occur on separate, distinct occasions, rather than multiple fractures occurring at the same time, but they may affect the same bone(s) multiple times. There is no required period between the incidents of fracture(s), but they must all occur within a 12-month period; for example, separate incidents may occur within hours or days of each other. However, the associated limitation(s) of function must last, or be expected to last, at least 12 months.

K. *What do we consider when we evaluate amputation due to any cause (1.20)?*

1. *General.* We consider amputation (the full or partial loss or absence of any extremity) due to any cause, including trauma, congenital abnormality or absence, surgery for treatment of conditions such as cancer or infection, or complications of peripheral vascular disease or diabetes mellitus.

2. *Amputation of both upper extremities (1.20A).* Upper extremity amputations, for the purposes of this listing, may occur at any level above the wrists (carpal joints), up to and including disarticulation of the shoulder (glenohumeral) joint. We do not evaluate amputations below the wrists under this listing, because the resulting limitation of function of the thumb(s), finger(s), or hand(s) will vary, depending on the extent of loss and corresponding effect on fine and gross movements (see 1.00E3). For amputations below the wrist, we will follow the remaining steps of the sequential evaluation process (see §§ 404.1520 and 416.920 of this chapter).

3. *Hemipelvectomy or hip disarticulation (1.20B).* Hemipelvectomy involves amputation of an entire lower extremity through the sacroiliac joint. Hip disarticulation involves amputation of an entire lower extremity through the hip joint capsule and closure of the remaining musculature over the exposed acetabular bone.

4. *Amputation of one upper extremity at any level above the wrist and one lower extremity at or above the ankle (1.20C).* We evaluate the absence of one upper extremity and one lower extremity with regard to whether you have a documented medical need (see 1.00C6a) for a one-handed assistive device (see 1.00C6d), such as a cane or crutch. In this situation, you may wear a prosthesis (see 1.00C6b) on your lower extremity, but nevertheless have a documented medical need for a one-handed assistive device. If you do, you would need to use your other upper extremity to hold the assistive device, making the extremity unavailable to perform other fine and gross movements (see 1.00E3) such as carrying. In such a case, your disorder would meet this listing.

5. *Amputation of one or both lower extremities at or above the ankle (tarsal joint) (1.20D).* When we evaluate amputations of one or both lower extremities:

a. We consider the condition of your residual limb(s), and whether you can wear a prosthesis(es) (see 1.00C6b). When you have a prosthesis(es), we will examine your residual limb with the prosthesis(es) in place. If you are unable to use a prosthesis(es) because of residual limb complications that have lasted, or are expected to last, for at least 12 months, and you are not currently undergoing surgical management (see 1.00L) of your condition, we evaluate your disorder under this listing.

b. Under 1.20D ''Amputation of one or both lower extremities at or above the ankle (tarsal joint),'' we consider whether you have a documented medical need (see 1.00C6a) for a hand-held assistive device(s) (1.00C) and your ability to walk with the device(s).

c. If you have a non-healing residual limb(s) and are receiving ongoing surgical treatment expected to re-establish or improve function, and that ongoing surgical treatment has not ended, or is not expected to end, within at least 12 months of the initiation of the surgical management (see 1.00L1), we evaluate your disorder under 1.21 *Soft tissue injury or abnormality under continuing surgical management.*

L. *What do we consider when we evaluate soft tissue injuries or abnormalities under continuing surgical management (1.21)?*

1. *General.*

a. We consider any soft tissue injury or abnormality involving the soft tissues of the body, whether congenital or acquired, when an acceptable medical source(s) documents the need for ongoing surgical procedures and associated medical treatments to restore function of the affected body part(s). Surgical management includes the surgery(-ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

b. Surgical procedures and associated treatments typically take place over extended periods, which may render you unable to perform work-related activity on a sustained basis. To document such inability, we must have evidence from an acceptable medical source(s) confirming that the surgical management has continued, or is expected to continue, for at least 12 months from the date of the first surgical intervention. These procedures and treatments must be directed toward saving, reconstructing, or replacing the affected part of the body to re-establish or improve its function, and not for cosmetic appearances alone.

c. Examples include malformations, third and fourth degree burns, crush injuries, craniofacial injuries, avulsive injuries, and amputations with complications of the residual limb(s).

d. We evaluate skeletal spine abnormalities or injuries under 1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s),* or 1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina,* as appropriate. We evaluate abnormalities or injuries of bones in the lower extremities under 1.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint,* 1.18 *Abnormality of a major joint(s) in any extremity,* or 1.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.* We evaluate abnormalities or injuries of bones in the upper extremities under 1.18 *Abnormality of a major joint(s) in any extremity,* or 1.23 *Non-healing or complex fracture of an upper extremity.*

2. *Documentation.* In addition to the objective medical evidence we need to establish your soft tissue injury or abnormality, we also need all of the following medically documented evidence about your continuing surgical management:

a. Operative reports and related laboratory findings;

b. Records of post-surgical procedures;

c. Records of any surgical or medical complications (for example, related infections or systemic illnesses);

d. Records of any prolonged post-operative recovery periods and related treatments (for example, surgeries and treatments for burns);

e. An acceptable medical source's plans for additional surgeries; and

f. Records detailing any other factors that have delayed, or that an acceptable medical source expects to delay, the saving, restoring, or replacing of the involved part for a continuous period of at least 12 months following the initiation of the surgical management.

3. *Burns.* Third- and fourth-degree burns damage or destroy nerve tissue, reducing or preventing transmission of signals through those nerves. Such burns frequently require multiple surgical procedures and related therapies to re-establish or improve function, which we evaluate under 1.21 *Soft tissue injury or abnormality under continuing surgical management.* When burns are no longer under continuing surgical management, we evaluate the residual impairment(s) (see 1.00O). When the residual impairment(s) affects the musculoskeletal system, as often occurs in third and fourth degree burns, it can result in permanent musculoskeletal tissue loss, joint contractures, or loss of extremities. We will evaluate such impairments under the relevant musculoskeletal listing(s), for example, 1.18 *Abnormality of a major joint(s) in any extremity* or 1.20 *Amputation due to any cause.* When the residual impairment(s) involves another body system(s), we will evaluate the impairment(s) under the relevant body system listing (for example, 8.08 *Burns*).

4. *Craniofacial injuries.* Surgeons may treat craniofacial injuries with multiple surgical procedures. These injuries may affect vision, hearing, speech, and the initiation of the digestive process, including mastication. When the craniofacial injury-related residual impairment(s) involves another body system(s), we will evaluate the impairment(s) under the relevant body system listings. See 1.00O regarding evaluation of residual impairment(s).

M. *What do we consider when we evaluate non-healing or complex fractures of the*

femur, tibia, pelvis, or one or more of the tarsal bones (1.22)?

1. We evaluate a non-healing (nonunion) or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones with regard to whether you have a documented medical need (see 1.00C6a) for a bilateral (two-handed) assistive device (see 1.00C6d), such as a walker or bilateral crutches.

2. *Non-healing fracture.* A non-healing fracture is a fracture that has failed to unite completely. Nonunion is usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no progressive signs of healing for a minimum of 3 months.

3. *Complex fracture.* A fracture is complex when one or more of the following occur:

a. Comminuted (broken into many pieces) bone fragments,

b. Multiple fractures in a single bone,

c. Bone loss due to severe trauma,

d. Damage to the surrounding soft tissue,

e. Severe cartilage damage to the associated joint, or

f. Dislocation of the associated joint.

4. When a complex fracture involves soft tissue damage, the treatment may involve continuing surgical management to restore or improve functioning. In such cases, we may evaluate the fracture(s) under 1.21 *Soft tissue injury or abnormality under continuing surgical management.*

N. *What do we consider when we evaluate non-healing or complex fractures of an upper extremity (1.23)?*

1. We evaluate a non-healing (nonunion) or complex fracture of an upper extremity under continuing surgical management (see 1.00L1a) with regard to whether you have an inability to use both upper extremities to independently initiate, sustain, and complete fine and gross movements.

2. *Non-healing fracture.* A non-healing fracture is a fracture that has failed to unite completely. Nonunion is usually established when a minimum of 9 months have elapsed since the injury and the fracture site has shown no progressive signs of healing for a minimum of 3 months.

3. *Complex fracture.* A fracture is complex when one or more of the following occur:

a. Comminuted (broken into many pieces) bone fragments,

b. Multiple fractures in a single bone,

c. Bone loss due to severe trauma,

d. Damage to the surrounding soft tissue,

e. Severe cartilage damage to the associated joint, or

f. Dislocation of the associated joint.

O. *How do we determine when your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management or you have received maximum therapeutic benefit?*

1. Your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management when the last surgical procedure or medical treatment directed toward the re-establishment or improvement of function of the involved part has occurred. We will find that you have received maximum therapeutic benefit from treatment if there are no significant changes in physical findings or on appropriate imaging for any 6-month period after the last surgical procedure or medical treatment. We may also find that you have received maximum therapeutic benefit if your medical source(s) indicates that further improvement is not expected after the last surgical procedure or medical treatment.

2. When you have received maximum therapeutic benefit from treatment, we will evaluate any impairment-related residual symptoms, signs, and laboratory findings (including those on imaging), any complications associated with your surgical procedures or medical treatments, and any residual limitations in your functioning. Depending upon all of those factors, we may find that your musculoskeletal impairment is no longer severe.

3. If your impairment(s) remains severe, we will evaluate your residual limitations and all other impairment-related factors to determine whether your musculoskeletal disorder meets or medically equals another listing. If it does not, we will follow the remaining steps of the sequential evaluation process to determine whether you have the residual functional capacity (RFC) to engage in substantial gainful activity. If your impairment involves burns and remains severe, we will follow the above sequence by evaluating your impairment as described in 1.00L3.

P. *How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment?*

1. You may not have received ongoing treatment or may not have an ongoing relationship with the medical community despite having a musculoskeletal disorder(s). In either of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. We may therefore ask you to attend a consultative examination to determine the severity and potential duration of your disorder (see §§ 404.1519a(b) and 416.919a(b) of this chapter).

2. In some instances, we may be able to assess the severity and duration of your musculoskeletal disorder based on your medical record and current evidence alone. If the information in your case record is not sufficient or appropriate to show that you have a musculoskeletal disorder that meets the criteria of one of the musculoskeletal disorders listings, we will follow the rules in 1.00R.

Q. *How do we evaluate substance use disorders that co-exist with a musculoskeletal disorder?*

If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder that co-exists with your musculoskeletal disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability (see §§ 404.1535 and 416.935 of this chapter).

R. *How do we evaluate disorders that do not meet one of the musculoskeletal listings?*

1. These listings are only examples of musculoskeletal disorders that we consider severe enough to prevent your ability to engage in any gainful activity. If your musculoskeletal disorder(s) does not meet the criteria of any of these listings, we will consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet any listing, we will determine whether your impairment(s) medically equals a listing. See §§ 404.1526 and 416.926 of this chapter. If it does not medically equal a listing, we will assess your RFC. See §§ 404.1545 and 416.945 of this chapter. To assess your RFC, we may require evidence in addition to, or different from, the types of evidence that we use to determine whether your impairment(s) meets or medically equals a listing. We will use the assessment of your RFC to evaluate your claim at the fourth, and if necessary, the fifth step of the sequential evaluation process to determine whether you can perform your past work or adjust to any other work, respectively. See §§ 404.1520 and 416.920 of this chapter.

3. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

1.01 Category of Impairments, Musculoskeletal Disorders

1.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s)* (see 1.00F), documented by A, B, C, and D:

A. Symptom(s) of neuro-anatomic (radicular) distribution of one or more of the following manifestations consistent with compromise of the affected nerve root(s):

1. Pain; or

2. Paresthesias; or

3. Muscle fatigue.

AND

B. Radicular neurological signs present during physical examination or testing and evidenced by 1, 2, and 4; or 1, 3, and 4 below:

1. Muscle weakness; and

2. Sensory changes evidenced by:

a. Decreased sensation; or

b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or

3. Decreased deep tendon reflexes; and

4. Sign(s) of nerve root irritation, tension, or compression, consistent with compromise of the affected nerve root (see 1.00F2).

AND

C. Findings on imaging consistent with compromise of a nerve root(s) in the cervical or lumbosacral spine (see 1.00C3).

AND

D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 1.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

1.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina* (see 1.00G), documented by A, B, C, and D:

A. Symptoms of neurological compromise, such as pain, manifested as:

1. Nonradicular distribution of pain in one or both lower extremities; or

2. Nonradicular distribution of sensory loss in one or both extremities; or

3. Neurogenic claudication.

AND

B. Nonradicular neurological signs present during physical examination or testing and evidenced by 1 and 2, or 1 and 3, below:

1. Muscle weakness; and

2. Sensory changes evidenced by:

a. Decreased sensation; or

b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or

c. Areflexia, trophic ulceration, or bladder or bowel incontinence.

3. Decreased deep tendon reflexes in one or both lower extremities.

AND

C. Findings on imaging or in an operative report consistent with compromise of the cauda equina with lumbar spinal stenosis.

AND

D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 1.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity.

1.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint* (see 1.00H), documented by A, B, and C:

A. Documented history of reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months.

AND

C. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 1.00E).

1.18 *Abnormality of a major joint(s) in any extremity* (see 1.00I), documented by A, B, C, and D:

A. Chronic joint pain or stiffness.

AND

B. Abnormal motion, instability, or immobility of the affected joint(s).

AND

C. Anatomical abnormality of the affected joint(s) noted on:

1. Physical examination (for example, subluxation, contracture, bony or fibrous ankylosis); or

2. Imaging (for example, joint space narrowing, bony destruction, or ankylosis or arthrodesis of the affected joint).

AND

D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 1.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

1.19 *Pathologic fractures due to any cause* (see 1.00J), documented by A and B:

A. Three or more medically documented pathologic fractures occurring on separate occasions within a 12-month period;

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 1.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

1.20 *Amputation due to any cause* (see 1.00K), documented by A, B, C, or D:

A. Amputation of both upper extremities, occurring at any level above the wrists (carpal joints), up to and including the shoulder (glenohumeral) joint.

OR

B. Hemipelvectomy or hip disarticulation.

OR

C. Amputation of one upper extremity, occurring at any level above the wrist (carpal joints), and one lower extremity at or above the ankle (tarsal joint), and medical documentation of one the following (see 1.00E):

1. The documented medical need for a one-handed assistive device requiring the use of the other upper extremity; or

2. The inability to use the remaining upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

OR

D. Amputation of one or both lower extremities at or above the ankle (tarsal joint), with complications of the residual limb that have lasted or can be expected to last for at least 12 months, and medical documentation of both 1 and 2 (see 1.00E):

1. The inability to use a prosthetic device(s); and

2. The documented medical need for a walker, bilateral canes, or bilateral crutches.

1.21 *Soft tissue injury or abnormality under continuing surgical management* (see 1.00L), documented by A, B, and C in the medical record:

A. Evidence confirms ongoing surgical management directed towards saving, reconstructing, or replacing the affected part of the body.

AND

B. The surgical management has been, or is expected to be, ongoing for at least 12 months.

AND

C. Maximum benefit from therapy has not yet been achieved.

1.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones* (see 1.00M), documented by A and B and C:

A. Solid union not evident on appropriate medically acceptable imaging and not clinically solid;

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months,

AND

C. Medical documentation of medical need for a walker, bilateral canes, or bilateral crutches (see 1.00E).

1.23 *Non-healing or complex fracture of an upper extremity* (see 1.00N), documented by A and B and C:

A. Nonunion of a fracture, or complex fracture of the shaft of the humerus, radius, or ulna, under continuing surgical management, as defined in 1.00O, directed toward restoration of functional use of the extremity;

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months;

AND

C. Medical documentation of at least one of the following (see 1.00E):

1. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

2. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and

complete work-related activities involving fine and gross movements.

* * * * *

4.00 CARDIOVASCULAR SYSTEM

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G. *Evaluating Peripheral Vascular Disease*

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4. *What is lymphedema and how will we evaluate it?*

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b. * * * We will evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema medically equals a cardiovascular listing, such as 4.11 *Chronic venous insufficiency,* or a musculoskeletal listing, such as 1.18 *Abnormality of a major joint(s) in any extremity.* * * *

* * * * *

14.00 IMMUNE SYSTEM DISORDERS

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C. *Definitions*

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2. *Assistive device(s)* has the same meaning as in 1.00C6a.

* * * * *

5. *Documented medical need* has the same meaning as in 1.00C6a.

* * * * *

8. *Fine and gross movements* has the same meaning as in 1.00E3.

9. *Hand-held assistive device* has the same meaning as in 1.00C6d.

10. *Major joint of an upper or lower extremity* has the same meaning as in 1.00I1.

* * * * *

D. *How do we document and evaluate the listed autoimmune disorders?*

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4. *Polymyositis and dermatomyositis (14.05).*

* * * * *

c. * * *

(i) Weakness of your pelvic girdle muscles that results in your inability to rise independently from a squatting or sitting position or to climb stairs may be an indication that you are unable to walk without physical or mechanical assistance. * * *

* * * * *

d. * * *

6. * * *

a. *General.* * * * Clinically, inflammation of major joints in an upper or lower extremity may be the dominant manifestation causing difficulties with walking or performing fine and gross movements; there may be joint pain, swelling, and tenderness. The arthritis may affect other joints, or cause less limitation in walking or performing fine and gross movements. * * *

* * * * *

e. * * *

(i) Listing-level severity in 14.09 *Inflammatory arthritis* is shown by the presence of an impairment-related, significant limitation cited in the criteria of these listings. In 14.09A, listing-level severity is satisfied with persistent inflammation or deformity in one major joint in a lower extremity resulting in a documented medical need for a walker, bilateral canes, or bilateral crutches as required in 14.09A1, or one major joint in each upper extremity resulting in an impairment-related, significant limitation in the ability to perform fine and gross movements as required in 14.09A2. In 14.09C1, if you have the required ankylosis (fixation) of your cervical or dorsolumbar spine, we will find that you have an impairment-related significant limitation in your ability to see in front of you, above you, and to the side. Therefore, a listing-level impairment in the ability to walk is implicit in 14.09C1, even though you might not require bilateral upper limb assistance.

(ii) Listing-level severity is shown in 14.09B, 14.09C2, and 14.09D by inflammatory arthritis that involves various combinations of complications of one or more major joints in an upper or lower extremity or other joints, such as inflammation or deformity, extra-articular features, repeated manifestations, and constitutional symptoms or signs. * * *

* * * * *

14.04 *Systemic sclerosis (scleroderma).* As described in 14.00D3. With:

* * * * *

B. One of the following:

1. Toe contractures or fixed deformity of one or both feet, resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 14.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 14.00C9) that requires the use of the other upper extremity; or

2. Finger contractures or fixed deformity in both hands, resulting in an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements; or

3. Atrophy with irreversible damage in one or both lower extremities, resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 14.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 14.00C9) that requires the use of the other upper extremity; or

4. Atrophy with irreversible damage in both upper extremities, resulting in an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

OR

C. Raynaud's phenomenon, characterized by:

* * * * *

2. Ischemia with ulcerations of toes or fingers, resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 14.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 14.00C9) that requires the use of the other upper extremity; or

c. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

* * * * *

14.05 *Polymyositis and dermatomyositis.* As described in 14.00D4. With:

A. Proximal limb-girdle (pelvic or shoulder) muscle weakness, resulting in one of the following:

1. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 14.00C9); or

2. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 14.00C9) that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

* * * * *

14.09 *Inflammatory arthritis.* As described in 14.00D6. With:

A. Persistent inflammation or persistent deformity of:

1. One or more major joints in a lower extremity(ies) resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 14.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 14.00C9) that requires the use of the other upper extremity; or

2. One or more major joints in each upper extremity resulting in an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

OR

B. Inflammation or deformity in one or more major joints of an upper or lower extremity(ies) with: * * *

* * * * *

Part B

* * * * *

101.00 Musculoskeletal Disorders.

* * * * *

101.00 Musculoskeletal Disorders

A. *Which disorders do we evaluate under these listings?*

1. We evaluate disorders of the skeletal spine (vertebral column) or of the upper or lower extremities that affect musculoskeletal functioning in the musculoskeletal body system listings. We use the term ''skeletal'' when we are referring to the structure of the bony skeleton. The skeletal spine refers to the bony structures, ligaments, and discs making up the spine. We refer to the ''skeletal'' spine in some musculoskeletal listings to differentiate it from the neurological spine (see 101.00B1). Disorders may be congenital or acquired, and may include deformities, amputations, or other musculoskeletal abnormalities. These disorders may involve the bones or major joints; or the tendons, ligaments, muscles, or other soft tissues.

2. We also evaluate soft tissue abnormalities or injuries (including burns) that are under continuing surgical management (see 101.00L). The abnormalities or injuries may affect any part of the body, including the face and skull.

B. *Which related disorders do we evaluate under other listings?*

1. We evaluate a disorder or injury of the skeletal spine that results in damage to, and neurological dysfunction of, the spinal cord and its associated nerves (for example, paraplegia or quadriplegia) under the criteria in 111.00 *Neurological Disorders.*

2. We evaluate inflammatory arthritis (for example, rheumatoid arthritis) under the criteria in 114.00 *Immune System Disorders.*

3. We evaluate curvatures of the skeletal spine under these musculoskeletal disorders listings and other listings as appropriate for the affected body system. Curvatures of the skeletal spine that affect musculoskeletal functioning are evaluated under 101.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s).* If a curvature of the skeletal spine is under continuing surgical management, we can evaluate it for medical equivalence to 101.21 *Soft tissue injury or abnormality under continuing surgical management.* Skeletal curvatures may also adversely affect functioning in body systems other than the musculoskeletal system. For example, the curvature may interfere with your ability to breathe (see 103.00 *Respiratory Disorders*); there may be impaired myocardial function (see 104.00 *Cardiovascular System*); or there may be disfigurement resulting in social withdrawal or depression (see 112.00 *Mental Disorders*).

4. We evaluate non-healing or pathological fractures due to cancer, whether it is a primary site or metastases, under the criteria in 113.00 *Cancer (Malignant Neoplastic Diseases).*

5. We evaluate the leg pain associated with peripheral vascular claudication under the criteria in 104.00 *Cardiovascular System.*

6. We evaluate burns that do not require continuing surgical management under the criteria in 108.00 *Skin Disorders.*

C. *What evidence do we need to evaluate your musculoskeletal disorder under these listings?*

1. *General.* To establish the presence of a musculoskeletal disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source who has examined you for the disorder. To assess the severity and duration of your disorder, we evaluate evidence from both medical and nonmedical sources who can describe how you function. If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 101.00Q *How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment?* We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 416.902, 416.912, 416.913, 416.913a, and 416.920b of this chapter. For our rules on evidence about your symptoms, see § 416.929 of this chapter.

2. *Physical examination report(s).* In the report(s) of your physical examination, we need a detailed description of the orthopedic, neurologic, or other objective clinical findings appropriate to your specific musculoskeletal disorder. We require objective clinical findings from the medical source's direct observations during your physical examination, not simply his or her report of your statements about your symptoms and limitations. When the medical source reports that a clinical test sign(s) is positive, unless we have evidence to the contrary, we will assume that he or she performed the test properly. For instance, we will assume a straight-leg raising test was conducted properly, *i.e.,* in a sitting and supine position, even if the medical source does not specify the positions in which the test was performed. In the absence of evidence to the contrary, we will accept the medical source's interpretation of the test. If you use an assistive device (see 101.00C6), the report must support the medical need for the device. If reduction in muscle strength is a factor, we require medical documentation of measurement of the strength of the muscle(s) in question, generally based on a grading system of 0 to 5. Zero (0) indicates complete loss of strength and 5 indicates maximum strength, consistent with Table 1 below. The documentation should also include measurements of grip and pinch strength, if there is evidence of involvement of one or both hands.

TABLE 1

Grading Scale of Muscle Function: 0 to 5

0	None	No visible or palpable contraction.
1	Trace	Visible or palpable contraction with no motion.
2	Poor	Active range of motion (ROM) with gravity eliminated.
3	Fair	Active ROM against gravity only, without resistance.
4	Good	Active ROM against gravity, moderate resistance.
5	Normal	Active ROM against gravity, maximum resistance.

3. *Laboratory findings: Imaging and other diagnostic tests*

a. Imaging refers to medical imaging techniques, such as x-ray, computed tomography (CT), magnetic resonance imaging (MRI), and radionuclide scanning. For the purpose of these listings, the imaging technique(s) must be consistent with the generally accepted standards of medical knowledge and clinical practice.

b. Findings on imaging must have lasted, or must be expected to last, for a continuous period of at least 12 months.

c. Imaging and other diagnostic tests can provide evidence of physical abnormalities; however, they may correlate poorly with your symptoms, including pain, or with your musculoskeletal functioning. Accordingly, we cannot use such tests as a substitute for physical examination findings about your ability to function, nor can we infer severity or functional limitations based solely on such tests.

d. For our policies about when we will purchase imaging and other diagnostic tests, see §§ 416.919k and 416.919m of this chapter.

4. *Operative reports.* If you have had a surgical procedure(s), we need either the operative reports, including details of the findings at surgery and information about any medical complications that may have occurred, or confirmatory evidence of the surgical procedure(s) from a medical source (for example, detailed follow-up reports or notations in the medical records concerning your past medical history).

5. *Effects of treatment*

a. *General.* Treatments for musculoskeletal disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your musculoskeletal disorder, and on your musculoskeletal functioning.

b. *Response to treatment.* To evaluate your musculoskeletal functioning in response to treatment, we need specific information related to your impairment, including the following: A description of your medications, including frequency of administration; the type and frequency of therapy you receive; and a description of your response to treatment and any complications you experience related to your impairment. The effects of treatment may be temporary or long-term. We need information over a sufficient period to determine the effect of

treatment on your current musculoskeletal functioning and to permit reasonable projections about your future functioning. In some cases, we will need additional evidence to make an assessment about your response to treatment. Depending upon the timing of this treatment in relation to the alleged onset date of disability, we may need to defer evaluation of the impairment for a period of up to 3 months from the date treatment began to permit consideration of treatment effects, unless we can make a determination or decision using the evidence we have.

6. *Assistive devices*

a. *General.* An assistive device, for the purposes of these listings, is any device that is used to improve stability, dexterity, or mobility. An assistive device can be worn (see 101.00C6b and c), or hand-held (see 101.00C6d). If you use any type of assistive device(s), we need evidence from a medical source regarding the documented medical need for the device(s). When we use the term ''documented medical need,'' we mean that there is evidence from a medical source(s) in the medical record that supports your need for an assistive device (see § 416.913 of this chapter). The evidence must include documentation from a medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device, and supporting the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

b. *Prosthesis(es).* A prosthesis is a wearable device, such as an artificial limb, that takes the place of an absent body part. We need evidence from a medical source documenting your ability to walk, or to perform fine and gross movements (see 101.00E4), with the prosthesis(es) in place. When amputation(s) involves a lower extremity or extremities, it is not necessary to evaluate your ability to walk without the prosthesis(es) in place. If you cannot use your prosthesis(es) due to complications affecting your residual limb(s), we need documentation from a medical source regarding the condition of your residual limb(s) and the medical basis for your inability to use the prosthesis(es).

c. *Orthosis(es).* An orthosis is a wearable device that prevents or corrects a dysfunction or deformity by aligning or supporting the affected body part. An orthosis may also be referred to as a ''brace.'' If you have an orthosis(es), we need evidence from a medical source documenting your ability to walk, or to perform fine and gross movements, with the orthosis(es) in place. If you cannot use your orthosis(es), we need evidence from a medical source documenting the medical basis for your inability to use the device(s).

d. *Hand-held assistive devices.* Hand-held assistive devices include canes, crutches, or walkers, and are carried in your hand(s) to support or aid you in walking. When you require a one-handed assistive device for ambulation, such as a cane or single crutch, and your other upper extremity has limitations preventing its use for fine or gross movement(s) (see 101.00E4), the need for the assistive device limits the use of both upper extremities. If you use a hand-held assistive device, we need evidence from a medical source documenting your need for the device(s) and describing how you walk with the device(s).

7. *Longitudinal evidence*

a. We generally need a longitudinal medical record to assess the duration of your musculoskeletal disorder, because symptoms, signs, and laboratory findings related to most musculoskeletal disorders may wax and wane, may improve over time, or may respond to treatment. By providing evidence over an extended period, the medical record will show whether your musculoskeletal functioning is improving, worsening, or unchanging.

b. For 101.19 *Pathologic fractures due to any cause* and 101.21 *Soft tissue injury or abnormality under continuing surgical management,* the required 12-month duration period is stated in the listing itself. For 101.20A (amputation of both upper extremities) or 101.20B (hemipelvectomy or hip disarticulation), we presume satisfaction of the duration requirement.

c. For all listings not referenced in 101.00C7b above, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. When we use the term ''close proximity of time,'' we mean that all of the relevant criteria have to appear in the medical record within a period not to exceed 4 months of one another. When the criterion in question is imaging, we mean those findings on imaging that we could reasonably expect to have been present at the date of impairment or date of onset. To meet a listing that uses the word ''and'' or ''AND'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

8. *Surgical treatment*

For some musculoskeletal disorders, a medical source may recommend surgery. If you have not yet had the recommended surgery, we will not deny your claim based on an assumption that surgery will resolve or improve your disorder. We will assess each case on an individual basis. Depending on your response to treatment, or depending on your medical sources' treatment plans, we may defer our findings regarding the effect of surgical intervention until a sufficient period has passed to permit proper consideration or judgment about your future functioning. See 101.00C5b *Response to treatment.*

D. *How do we consider symptoms, including pain, under these listings?*

1. Individuals with musculoskeletal disorders may experience pain or other symptoms; however, statements alone about your pain or other symptoms cannot establish that you are disabled. Further, an alleged or reported increase in the intensity of a symptom, such as pain, no matter how severe, cannot be substituted for a medical sign or diagnostic finding present in the listing criteria. Pain is included as just one consideration in paragraph A in listings 101.15, 101.16, and 101.18, but is not required to satisfy the criteria in these listings. Examples of other findings that will satisfy the criteria in paragraph A include muscle fatigue, nonradicular distribution of sensory loss in one or both extremities, and joint stiffness.

2. To consider your pain, we require objective medical evidence from an acceptable medical source showing the existence of a medically determinable impairment(s) (MDI) that could reasonably be expected to produce the pain. When your musculoskeletal MDI could reasonably be expected to produce the pain or other symptoms alleged, we consider all your symptoms, including pain, and the extent to which your symptoms can reasonably be accepted as consistent with all of the objective medical evidence, including medical signs and laboratory or diagnostic findings. See § 416.929 of this chapter for information on how we evaluate pain or other symptoms related to a musculoskeletal impairment.

E. *How do we use the functional criteria under these listings?*

1. *General.* We will determine that your musculoskeletal disorder meets a listing if it satisfies the medical criteria; includes at least one of the functional criteria, if included in the listing; and satisfies the 12-month duration requirement. We will use the relevant evidence that we have to compare your musculoskeletal functioning to the functioning of children your age who do not have impairments. For example, if you are able to walk at home without an assistive device, we will not consider that to be conclusive evidence that you have similar functioning to other children your age who do not have impairments.

2. *Medical and functional criteria, birth to attainment of age 3.* The medical and functional criteria for children in this age group are in 101.24 *Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay.*

3. *Functional criteria, age 3 to attainment of age 18.* The functional criteria are based on impairment-related physical limitations in your ability to use both upper extremities, one or both lower extremities, or a combination of one upper and one lower extremity. A musculoskeletal disorder satisfies the functional criteria of a listing when the medical documentation shows the presence of at least one of the impairment-related limitations cited in the listing. The functional criteria require impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

a. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d);

b. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4), and a documented medical need (see 101.00C6a) for a one-handed assistive device (see 101.00C6d) that requires the use of your other upper extremity;

c. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4).

4. *Fine and gross movements.* Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional abilities such as lifting, carrying, pushing, and pulling.

5. *When we do not use the functional criteria.* We do not use the functional criteria to evaluate amputation of both upper extremities under 101.20A, hemipelvectomy or hip disarticulation under 101.20B, and soft tissue injuries or abnormalities under continuing surgical management under 101.21.

F. *What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (101.15)?*

1. *General.* We consider musculoskeletal disorders such as skeletal dysplasias, caudal regression syndrome, tethered spinal cord syndrome, vertebral slippage (spondylolisthesis), scoliosis, and vertebral fracture or dislocation. Spinal disorders may cause cervical or lumbar spine dysfunction when abnormalities of the skeletal spine compromise nerve roots of the cervical spine, a nerve root of the lumbar spine, or a nerve root of both cervical and lumbar spines.

2. *Compromise of a nerve root(s).* Compromise of a nerve root(s), sometimes referred to as ''nerve root impingement,'' is a term used when a physical object is seen pushing on the nerve root in an imaging study or during surgery. Objects such as tumors, herniated discs, foreign bodies, or arthritic spurs may cause compromise of a nerve root. It can occur when a musculoskeletal disorder produces irritation, inflammation, or compression of the nerve root(s) as it exits the skeletal spine between the vertebrae. Related symptoms must be associated with, or follow the path of, the specific nerve root(s), thereby presenting a neuro-anatomic (usually referred to as ''radicular'') distribution of symptoms and signs, including pain, paresthesia (for example, burning, prickling, or tingling), sensory loss, and usually muscle weakness specific to the affected nerve root(s).

a. *Compromise of unilateral nerve root of the cervical spine.* Compromise of a nerve root as it exits the cervical spine between the vertebrae may affect the functioning of the associated upper extremity. The clinical examination reproduces the related symptoms based on radicular signs and clinical tests (for example, a positive Spurling's Test) appropriate to the specific cervical nerve root.

b. *Compromise of bilateral nerve roots of the cervical spine.* Although uncommon, if compromise of a nerve root occurs on both sides of the cervical spinal column, functioning of both upper extremities may be limited.

c. *Compromise of a nerve root(s) of the lumbar spine.* Compromise of a nerve root as it exits the lumbar spine between the vertebrae may limit the functioning of the associated lower extremity. The clinical examination reproduces the related symptoms based on radicular signs and clinical tests. When a nerve root of the lumbar spine is compromised, we require a positive straight-leg raising test (also known as a Lasegue test) in both supine and sitting positions appropriate to the specific lumbar nerve root that is compromised. (See 101.00C2 for guidance on interpreting information from a physical examination report.)

G. *What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (101.16)?*

1. We consider the limiting effects of pain, sensory changes, and muscle weakness caused by compromise of the cauda equina due to lumbar spinal stenosis. The cauda equina is a bundle of nerve roots that descends from the lower part of the spinal cord. Lumbar spinal stenosis can compress the nerves of the cauda equina, causing sensory changes and muscle weakness that may affect your ability to stand or walk. Pain related to compromise of the cauda equina is ''nonradicular,'' because it is not typically associated with a specific nerve root (as is radicular pain in the cervical or lumbar spine).

2. Compromise of the cauda equina due to spinal stenosis can affect your ability to walk because of neurogenic claudication (also known as pseudoclaudication), a disorder usually causing non-radicular pain that starts in the low back and radiates bilaterally (or less commonly, unilaterally) into the buttocks and lower extremities (or extremity). Extension of the lumbar spine, as when walking or merely standing, provokes the pain of neurogenic claudication. It is relieved by forward flexion of the lumbar spine or by sitting.

H. *What do we consider when we evaluate reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (101.17)?*

1. We consider reconstructive surgery or surgical arthrodesis when an acceptable medical source(s) documents the surgical procedure(s) and associated medical treatments to restore function of the affected body part(s). The reconstructive surgery may be a single event or it may be a series of procedures directed toward the salvage or restoration of functional use of the affected joint.

2. *Major weight-bearing joints.* The major weight-bearing joints are the hip, knee, and ankle-foot. The ankle and foot are considered together as one major joint.

3. *Surgical arthrodesis.* Surgical arthrodesis is the artificial fusion of the bones that form a joint, essentially eliminating the joint.

I. *What do we consider when we evaluate abnormality of a major joint(s) in any extremity (101.18)?*

1. *General.* We consider musculoskeletal disorders that produce anatomical abnormalities of major joints of the extremities, resulting in functional abnormalities in the upper or lower extremities (for example, infections of bones and joints). Major joint of an upper extremity refers to the shoulder, elbow, and wrist-hand. We consider the wrist and hand together as one major joint. Major joint of a lower extremity refers to the hip, knee, and ankle-foot. We consider the ankle and hindfoot together as one major joint, because it is necessary for walking. Abnormalities affecting the joints may include ligamentous laxity or rupture, soft tissue contracture, or tendon rupture, and can cause muscle weakness of the affected body part.

2. *How do we define abnormality in the extremities?* An anatomical abnormality in any extremity(ies) is one that is readily observable by a medical source during a physical examination (for example, subluxation or contracture), or is present on imaging (for example, ankylosis, bony destruction, joint space narrowing, or deformity). A functional abnormality is abnormal motion or instability of the affected part(s), including limitation of motion, excessive motion (hypermobility), movement outside the normal plane of motion for the joint (for example, lateral deviation), or fixation of the affected parts.

J. *What do we consider when we evaluate pathologic fractures due to any cause (101.19)?* We consider pathologic fractures of the bones in the skeletal spine, extremities, or other parts of the skeletal system. Pathologic fractures result from disorders that weaken the bones, making them vulnerable to breakage. For non-healing or complex traumatic fractures without accompanying pathology, see 101.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones,* or 101.23 *Non-healing fracture of an upper extremity.* Pathologic fractures may occur with osteoporosis, osteogenesis imperfecta or any other skeletal dysplasias, side effects of medications, and disorders of the endocrine or other body systems. They must occur on separate, distinct occasions, rather than multiple fractures occurring at the same time, but they may affect the same bone(s) multiple times. There is no required period between the incidents of fracture(s), but they must all occur within a 12-month period; for example, separate incidents may occur within hours or days of each other. However, the associated limitation(s) of function must last, or be expected to last, at least 12 months.

K. *What do we consider when we evaluate amputation due to any cause (101.20)?*

1. *General.* We consider amputations (the full or partial loss or absence of any extremity) due to any cause, including trauma, congenital abnormality or absence, or surgery for treatment of conditions such as cancer or infection.

2. *Amputation of both upper extremities (101.20A).* Upper extremity amputations, for the purposes of this listing, may occur at any level above the wrists (carpal joints), up to and including disarticulation of the shoulder (glenohumeral) joint. We do not evaluate amputations below the wrists under this listing, because the resulting limitation of function of the thumb(s), finger(s), or hand(s) will vary, depending on the extent of loss and corresponding effect on fine and gross

movements (see 101.00E4). For amputations below the wrist, we will follow our rules for determining functional equivalence to the listings (see § 416.926a of this chapter).

3. *Hemipelvectomy or hip disarticulation (101.20B).* Hemipelvectomy involves amputation of an entire lower extremity through the sacroiliac joint. Hip disarticulation involves amputation of an entire lower extremity through the hip joint capsule and closure of the remaining musculature over the exposed acetabular bone.

4. *Amputation of one upper extremity at any level above the wrist and one lower extremity at or above the ankle (101.20C).* We evaluate the absence of one upper extremity and one lower extremity with regard to whether you have a documented medical need (see 101.00C6a) for a one-handed assistive device (see 101.00C6d), such as a cane or crutch. In this situation, you may wear a prosthesis (see 101.00C6b) on your lower extremity, but nevertheless have a documented medical need for a one-handed assistive device. If you do, you would need to use your other upper extremity to hold the assistive device, making the extremity unavailable to perform other fine and gross movements (see 101.00E4) such as carrying. In such a case, your disorder would meet this listing.

5. *Amputation of one or both lower extremities at or above the ankle (tarsal joint), (101.20D).* When we evaluate amputations of one or both lower extremities:

a. We consider the condition of your residual limb(s), and whether you can wear a prosthesis(es) (see 101.00C6b). When you have a prosthesis(es), we will examine your residual limb with the prosthesis(es) in place. If you are unable to use a prosthesis(es) because of residual limb complications that have lasted, or are expected to last, for at least 12 months, and you are not currently undergoing surgical management (see 101.00L1) of your condition, we evaluate your disorder under this listing.

b. Under 101.20D ''Amputation of one or both lower extremities at or above the ankle (tarsal joint),'' we consider whether you have a documented medical need (see 101.00C6a) for a hand-held assistive device(s) (see 101.00C6d) and your ability to walk with the device(s).

c. If you have a non-healing residual limb(s) and are receiving ongoing surgical treatment expected to re-establish or improve function, and that ongoing surgical treatment has not ended, or is not expected to end, within at least 12 months of the initiation of the surgical management (see 101.00L1), we evaluate your disorder under 101.21 *Soft tissue injury or abnormality under continuing surgical management.*

L. *What do we consider when we evaluate soft tissue injury or abnormality under continuing surgical management (101.21)?*

1. *General.*

a. We consider any soft tissue injury or abnormality involving the soft tissues of the body, whether congenital or acquired, when an acceptable medical source(s) documents the need for ongoing surgical procedures and associated medical treatments to restore function of the affected body parts. Surgical management includes the surgery(-ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from therapy.

b. Surgical procedures and associated treatments typically take place over extended periods, which may render you unable to perform age-appropriate activity on a sustained basis. To document such inability, we must have evidence from an acceptable medical source(s) confirming that the surgical management has continued, or is expected to continue, for at least 12 months from the date of the first surgical intervention. These procedures and treatments must be directed toward saving, reconstructing, or replacing the affected part of the body to re-establish or improve its function, and not for cosmetic appearances alone.

c. Examples include malformations, third- and fourth-degree burns, crush injuries, craniofacial injuries, avulsive injuries, and amputations with complications of the residual limb(s).

d. We evaluate skeletal spine abnormalities or injuries under 101.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s)* or 101.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina,* as appropriate. We evaluate abnormalities or injuries of bones in the lower extremities under 101.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint,* 101.18 *Abnormality of a major joint(s) in any extremity,* or 101.22 *Non-healing fracture of the femur, tibia, pelvis, or one or more of the tarsal bones.* We evaluate abnormalities or injuries of bones in the upper extremities under 101.18 *Abnormality of a major joint(s) in any extremity,* or 101.23 *Non-healing or complex fracture of an upper extremity.*

2. *Documentation.* In addition to the objective medical evidence we need to establish your soft tissue injury or abnormality, we also need all of the following medically documented evidence about your continuing surgical management:

a. Operative reports and related laboratory findings;

b. Records of post-surgical procedures;

c. Records of any surgical or medical complications (for example, related infections or systemic illnesses);

d. Records of any prolonged post-operative recovery periods and related treatments (for example, surgeries and treatments for burns); and

e. An acceptable medical source's plans for additional surgeries;

f. Records detailing any other factors that have delayed, or that an acceptable medical source expects to delay, the saving, restoring, or replacing of the involved part for a continuous period of at least 12 months following the initiation of the surgical management.

3. *Burns.* Third- and fourth-degree burns damage or destroy nerve tissue, reducing or preventing transmission of signals through those nerves. Such burns frequently require multiple surgical procedures and related therapies to re-establish or improve function, which we evaluate under 101.21 *Soft tissue injury or abnormality under continuing surgical management.* When burns are no longer under continuing surgical management, we evaluate the residual impairment(s) (see 101.00P). When the residual impairment(s) affects the musculoskeletal system, as often occurs in third and fourth degree burns, it can result in permanent musculoskeletal tissue loss, joint contractures, or loss of extremities. We will evaluate such impairments under the relevant musculoskeletal listing(s), for example, 101.18 *Abnormality of a major joint(s) in any extremity* or 101.20 *Amputation due to any cause.* When the residual impairment(s) involves another body system(s), we will evaluate the impairment(s) under the relevant body system listing (for example, 108.08 *Burns*).

4. *Congenital abnormalities or craniofacial injuries.* Surgeons may treat craniofacial injuries or abnormalities with multiple surgical procedures. These injuries or abnormalities may affect vision, hearing, speech, and the initiation of the digestive process, including mastication. When the craniofacial injury-related or congenital residual impairment(s) involves another body system(s), we will evaluate the impairment(s) under the relevant body system listings. See 101.00P regarding evaluation of residual impairment(s).

M. *What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the tarsal bones (101.22)?*

1. We evaluate a non-healing (nonunion) or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones with regard to whether you have a documented medical need (see 101.00C6a) for a bilateral (two-handed) assistive device (see 101.00C6d), such as a walker or bilateral crutches.

2. *Non-healing fracture.* A non-healing fracture is a fracture that has failed to unite completely. Nonunion is usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no progressive signs of healing for a minimum of 3 months.

3. *Complex fracture.* A fracture is complex when one or more of the following occur:

a. Comminuted (broken into many pieces) bone fragments,

b. Multiple fractures in a single bone,

c. Bone loss due to severe trauma,

d. Damage to the surrounding soft tissue,

e. Severe cartilage damage to the associated joint, or

f. Dislocation of the associated joint.

4. When a complex fracture involves soft tissue damage, the treatment may involve continuing surgical management to restore or improve functioning. In such cases, we may evaluate the fracture(s) under 101.21 *Soft tissue injury or abnormality under continuing surgical management.*

N. *What do we consider when we evaluate non-healing or complex fractures of an upper extremity (101.23)?*

1. We evaluate a non-healing (nonunion) or complex fracture of an upper extremity under continuing surgical management (see 101.00L1a) with regard to whether you have an inability to use both upper extremities to

independently initiate, sustain, and complete fine and gross movements.

2. *Non-healing fracture.* A non-healing fracture is a fracture that has failed to unite completely. Nonunion is usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no progressive signs of healing for a minimum of 3 months.

3. *Complex fracture.* A fracture is complex when one or more of the following occur:

a. Comminuted (broken into many pieces) bone fragments

b. Multiple fractures in a single bone

c. Bone loss due to severe trauma

d. Damage to the surrounding soft tissue

e. Severe cartilage damage to the associated joint

f. Dislocation of the associated joint.

O. *What do we consider when we evaluate musculoskeletal disorders of infants and toddlers from birth to attainment of age 3 with developmental motor delay (101.24)?*

1. Under listing 101.24 *Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay,* we use reports from an acceptable medical source(s) to establish a diagnosis of delay in your motor development. To evaluate the severity level of your developmental motor delay, we accept developmental test reports from an acceptable medical source, or from early intervention specialists, physical and occupational therapists, and other sources.

a. If there is a standardized developmental assessment in your medical record, we will use the results to evaluate your developmental motor delay under 101.24A. Such an assessment compares your level of development to the level typically expected for children of your chronological age. If you were born prematurely, we use your corrected chronological age (CCA) for comparison. Your CCA is your chronological age adjusted by a period of gestational prematurity (CCA = (chronological age)—(number of weeks premature)) (see § 416.924b(b) of this chapter).

b. If there is no standardized developmental assessment in your medical record, we will use narrative developmental reports from a medical source(s) to evaluate your developmental motor delay under 101.24B. These reports must provide detailed information sufficient for us to assess the severity of your motor delay. If we cannot obtain sufficient detail from narrative reports, we may purchase standardized developmental assessments.

(i) A narrative developmental report is based on clinical observations, progress notes, and well-baby check-ups, and must include your developmental history; examination findings (with abnormal findings noted on repeated examinations); and an overall assessment of your development (that is, more than one or two isolated skills) by the medical source.

(ii) Some narrative developmental reports may include results from developmental screening tests, which can show that you are not developing or achieving skills within expected timeframes. Although medical sources may refer to screening test results as supporting evidence in the narrative developmental report, screening test results alone cannot establish a medically determinable impairment or the severity of developmental motor delay.

2. Examples of disorders we evaluate include arthrogryposis, clubfoot, osteogenesis imperfecta, caudal regression syndrome, fracture complications, disorders affecting the hip and pelvis, and complications associated with your disorder or its treatment. Some medical records may simply document your condition as ''developmental motor delay.''

P. *How do we determine when your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management or you have received maximum therapeutic benefit?*

1. Your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management when the last surgical procedure or medical treatment directed toward the re-establishment or improvement of function of the involved part has occurred. We will find that you have received maximum therapeutic benefit from treatment if there are no significant changes in physical findings or on appropriate imaging for any 6-month period after the last surgical procedure or medical treatment. We may also find that you have received maximum therapeutic benefit if your medical source(s) indicates that further improvement is not expected after the last surgical procedure or medical treatment.

2. When you have received maximum therapeutic benefit from treatment, we will evaluate any impairment-related residual symptoms, signs, and laboratory findings (including those on imaging), any complications associated with your surgical procedures or medical treatments, and any residual limitations in your functioning. Depending upon all of those factors, we may find that your musculoskeletal impairment is no longer severe.

3. If your impairment(s) remains severe, we will evaluate your residual limitations and all other impairment-related factors to determine whether your musculoskeletal disorder meets or medically equals another listing or functionally equals the listings. If your impairment involves burns and remains severe, we will follow the above sequence by evaluating your impairment as described in 101.00L3.

Q. *How do we evaluate the severity and duration of your established musculoskeletal disorder when there is no record of ongoing treatment?*

1. You may not have received ongoing treatment or may not have an ongoing relationship with the medical community despite having a musculoskeletal disorder(s). In either of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. We may therefore ask you to attend a consultative examination to determine the severity and potential duration of your disorder (see § 416.919a(b) of this chapter).

2. In some instances, we may be able to assess the severity and duration of your musculoskeletal disorder based on your medical record and current evidence alone. If the information in your case record is not sufficient or appropriate to show that you have a musculoskeletal disorder that meets the criteria of one of the musculoskeletal disorders listings, we will follow the rules in 101.00R.

R. *How do we evaluate disorders that do not meet one of the musculoskeletal listings?*

1. These listings are only examples of musculoskeletal disorders that we consider severe enough to result in marked and severe functional limitations. If your musculoskeletal disorder(s) does not meet the criteria of any of these listings, we will consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet any listing, we will determine whether your impairment(s) medically equals a listing (see § 416.926 of this chapter). If it does not medically equal a listing, we will determine whether it functionally equals the listings (see § 416.926a of this chapter).

3. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

101.01 Category of Impairments, Musculoskeletal Disorders

101.15 *Disorders of the skeletal spine resulting in compromise of a nerve root(s)* (see 101.00F), documented by A, B, C, and D:

A. Symptom(s) of neuro-anatomic (radicular) distribution of one or more of the following manifestations consistent with compromise of the affected nerve root(s):

1. Pain; or

2. Paresthesias; or

3. Muscle fatigue.

AND

B. Radicular neurological signs present during physical examination or testing and evidenced by 1, 2, and 4; or 1, 3, and 4 below:

1. Muscle weakness; and

2. Sensory changes evidenced by:

a. Decreased sensation; or

b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or

3. Decreased deep tendon reflexes; and

4. Sign(s) of nerve root irritation, tension, or compression, consistent with compromise of the affected nerve root (see 101.00F2).

AND

C. Findings on imaging consistent with compromise of a nerve root(s) in the cervical or lumbosacral spine (see 101.00C3).

AND

D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 101.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

101.16 *Lumbar spinal stenosis resulting in compromise of the cauda equina* (see 101.00G), documented by A, B, C, and D:

A. Symptoms of neurological compromise, such as pain, manifested as:

1. Nonradicular distribution of pain in one or both lower extremities; or

2. Nonradicular distribution of sensory loss in one or both extremities; or

3. Neurogenic claudication.

AND

B. Nonradicular neurological signs present during physical examination or testing and evidenced by 1 and 2, or 1 and 3, below:

1. Muscle weakness; and

2. Sensory changes evidenced by:

a. Decreased sensation; or

b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or

c. Areflexia, trophic ulceration, or bladder or bowel incontinence.

3. Decreased deep tendon reflexes in one or both lower extremities.

AND

C. Findings on imaging or in an operative report consistent with compromise of the cauda equina with lumbar spinal stenosis.

AND

D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 101.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity.

101.17 *Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint* (see 101.00H), documented by A and B and C:

A. Documented history of reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months.

AND

C. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 101.00E).

101.18 *Abnormality of a major joint(s) in any extremity* (see 101.00I), documented by A, B, C, and D:

A. Chronic joint pain or stiffness.

AND

B. Abnormal motion, instability, or immobility of the affected joint(s).

AND

C. Anatomical abnormality of the affected joint(s) noted on:

1. Physical examination (for example, subluxation, contracture, bony or fibrous ankylosis); or

2. Imaging (for example, joint space narrowing, bony destruction, or ankylosis or arthrodesis of the affected joint).

AND

D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 101.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

101.19 *Pathologic fractures due to any cause* (see 101.00J), documented by A and B:

A. Three or more medically documented pathologic fractures occurring on separate occasions within a 12-month period;

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, and medical documentation of at least one of the following (see 101.00E):

1. A documented medical need for a walker, bilateral canes, or bilateral crutches; or

2. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

101.20 *Amputation due to any cause* (see 101.00K), documented by A, B, C, or D:

A. Amputation of both upper extremities, occurring at any level above the wrists (carpal joints), up to and including the shoulder (glenohumeral) joint.

OR

B. Hemipelvectomy or hip disarticulation.

OR

C. Amputation of one upper extremity, occurring at any level above the wrist (carpal joints), and one lower extremity at or above the ankle (tarsal joint), and medical documentation of one the following (see 101.00E):

1. The documented medical need for a one-handed assistive device requiring the use of the other upper extremity, or

2. The inability to use the remaining upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

OR

D. Amputation of one or both lower extremities at or above the ankle (tarsal joint), with complications of the residual limb that have lasted or can be expected to last for at least 12 months, and medical documentation of both 1 and 2 (see 101.00E):

1. The inability to use a prosthetic device(s); and

2. The documented medical need for a walker, bilateral canes, or bilateral crutches.

101.21 *Soft tissue injury or abnormality under continuing surgical management* (see 101.00L), documented by A, B, and C in the medical record:

A. Evidence confirms ongoing surgical management directed towards saving, reconstructing, or replacing the affected part of the body.

AND

B. The surgical management has been, or is expected to be, ongoing for at least 12 months.

AND

C. Maximum benefit from therapy has not yet been achieved.

101.22 *Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the tarsal bones* (see 101.00M), documented by A and B and C:

A. Solid union not evident on appropriate medically acceptable imaging and not clinically solid;

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months,

AND

C. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 101.00E).

101.23 *Non-healing or complex fracture of an upper extremity* (see 101.00N), Documented by A and B and C:

A. Nonunion of a fracture, or complex fracture, of the shaft of the humerus, radius, or ulna, under continuing surgical management, as defined in 1.00P, directed toward restoration of functional use of the extremity;

AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months,

AND

C. Medical documentation of at least one of the following (see 101.00E):

1. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device that requires the use of the other upper extremity; or

2. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and

complete age-appropriate activities involving fine and gross movements.

101.24 *Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay* (see 101.00O), as documented by A or B:

A. A standardized developmental motor assessment that:

1. Shows motor development not more than one-half the level typically expected for child's age; or

2. Results in a valid score that is at least three standard deviations below the mean.

OR

B. Two narrative developmental reports that:

1. Are dated at least 120 days apart; and

2. Show motor development not more than one-half of the level typically expected for child's age.

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104.00 CARDIOVASCULAR SYSTEM

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F. *Evaluating Other Cardiovascular Impairments*

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9. *What is lymphedema and how will we evaluate it?*

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b. * * * We will evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema medically equals a cardiovascular listing, such as 4.11 *Chronic venous insufficiency,* or a musculoskeletal listing, such as 101.18 *Abnormality of a major joint(s) in any extremity.* * * *

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114.00 IMMUNE SYSTEM DISORDERS

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C. *Definitions*

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2. *Assistive device(s)* has the same meaning as in 101.00C6a.

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5. *Documented medical need* has the same meaning as in 101.00C6a.

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8. *Fine and gross movements* have the same meaning as in 101.00E4.

9. *Hand-held assistive device* has the same meaning as in 101.00C6d.

10. *Major joint of an upper or lower extremity* has the same meaning as in 101.00I1.

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D. *How do we document and evaluate the listed autoimmune disorders?*

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4. *Polymyositis and dermatomyositis (114.05).*

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c. *Additional information about how we evaluate polymyositis and dermatomyositis under the listings.*

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(ii) If you are of preschool age through adolescence (age 3 to attainment of age 18), weakness of your pelvic girdle muscles that results in your inability to rise independently from a squatting or sitting position or to climb stairs may be an indication that you are unable to walk without physical or mechanical assistance. * * *

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6. *Inflammatory arthritis (114.09).*

a. *General.* * * * Clinically, inflammation of major joints in an upper or lower extremity may be the dominant manifestation causing difficulties with walking or performing fine and gross movements; there may be joint pain, swelling, and tenderness. The arthritis may affect other joints, or cause less limitation in walking or performing fine and gross movements. * * *

* * * * *

e. *How we evaluate inflammatory arthritis under the listings.*

(i) Listing-level severity in 114.09 *Inflammatory arthritis* A and C1 is shown by the presence of an impairment-related, significant limitation cited in the criteria of these listings. In 114.09A, listing-level severity is satisfied with persistent inflammation or deformity in one major joint in a lower extremity resulting in a documented medical need for a walker, bilateral canes, or bilateral crutches as required in 114.09A1, or one major joint in each upper extremity resulting in an impairment-related, significant limitation in the ability to perform fine and gross movements as required in 114.09A2. In 114.09C1, if you have the required ankylosis (fixation) of your cervical or dorsolumbar spine, we will find that you have an impairment-related significant limitation in your ability to see in front of you, above you, and to the side. Therefore, a listing-level impairment in the ability to walk is implicit in 114.09C1, even though you might not require bilateral upper limb assistance.

(ii) Listing-level severity is shown in 114.09B and 114.09C2 by inflammatory arthritis that involves various combinations of complications of one or more major joints in an upper or lower extremity or other joints, such as inflammation or deformity, extra-articular features, repeated manifestations, and constitutional symptoms and signs. * * *

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114.01 Category of Impairments, Immune System Disorders

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114.04 *Systemic sclerosis (scleroderma).* As described in 114.00D3. With:

* * * * *

B. One of the following:

1. Toe contractures or fixed deformity of one or both feet, resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 114.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 114.00C9) that requires the use of the other upper extremity; or

2. Finger contractures or fixed deformity in both hands, resulting in an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements; or

3. Atrophy with irreversible damage in one or both lower extremities, resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 114.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 114.00C9) that requires the use of the other upper extremity; or

4. Atrophy with irreversible damage in both upper extremities, resulting in an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

OR

C. Raynaud's phenomenon, characterized by:

* * * * *

2. Ischemia with ulcerations of toes or fingers, resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 114.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 114.00C9) that requires the use of the other upper extremity; or

c. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

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114.05 *Polymyositis and dermatomyositis.* As described in 114.00D4. With:

A. Proximal limb-girdle (pelvic or shoulder) muscle weakness, resulting in one of the following:

1. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 114.00C9); or

2. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 114.00C9) that requires the use of the other upper extremity; or

3. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

* * * * *

114.09 *Inflammatory arthritis.* As described in 114.00D6. With:

A. Persistent inflammation or persistent deformity of:

1. One or more major joints in a lower extremity(ies) resulting in one of the following:

a. A documented medical need for a walker, bilateral canes, or bilateral crutches (see 114.00C9); or

b. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements, and a documented medical need for a one-handed assistive device (see 114.00C9) that requires the use of the other upper extremity; or

2. One or more major joints in each upper extremity resulting in an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

OR

B. Inflammation or deformity in one or more major joints of an upper or lower extremity(ies) with: * * *

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—[Amended]

■ 3. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383b); secs. 4(c) and 5, 6(c)-(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

■ 4. Amend § 416.926a by removing paragraph (m)(1) through (m)(2) and redesignating paragraphs (m)(3) through (m)(5) as (m)(1) through (m)(3).

[FR Doc. 2018–08889 Filed 5–4–18; 8:45 am]

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FEDERAL REGISTER

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Part IV

The President

Federal Register
Vol. 83, No. 88
Monday, May 7, 2018

Presidential Documents

Title 3—

The President

Proclamation 9739 of April 30, 2018

Adjusting Imports of Aluminum Into the United States

By the President of the United States of America

A Proclamation

1. On January 19, 2018, the Secretary of Commerce (Secretary) transmitted to me a report on his investigation into the effect of imports of aluminum articles on the national security of the United States under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862).

2. In Proclamation 9704 of March 8, 2018 (Adjusting Imports of Aluminum Into the United States), I concurred in the Secretary's finding that aluminum articles are being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States, and decided to adjust the imports of aluminum articles, as defined in clause 1 of Proclamation 9704, by imposing a 10 percent ad valorem tariff on such articles imported from all countries except Canada and Mexico. I further stated that any country with which we have a security relationship is welcome to discuss with the United States alternative ways to address the threatened impairment of the national security caused by imports from that country, and noted that, should the United States and any such country arrive at a satisfactory alternative means to address the threat to the national security such that I determine that imports from that country no longer threaten to impair the national security, I may remove or modify the restriction on aluminum articles imports from that country and, if necessary, adjust the tariff as it applies to other countries, as the national security interests of the United States require.

3. In Proclamation 9710 of March 22, 2018 (Adjusting Imports of Aluminum Into the United States), I noted the continuing discussions with the Argentine Republic (Argentina), the Commonwealth of Australia (Australia), the Federative Republic of Brazil (Brazil), Canada, Mexico, the Republic of Korea (South Korea), and the European Union (EU) on behalf of its member countries, on satisfactory alternative means to address the threatened impairment to the national security by imports of aluminum articles from those countries. Recognizing that each of these countries and the EU has an important security relationship with the United States, I determined that the necessary and appropriate means to address the threat to national security posed by imports of aluminum articles from these countries was to continue the ongoing discussions and to exempt aluminum articles imports from these countries from the tariff proclaimed in Proclamation 9704 until May 1, 2018.

4. The United States has agreed in principle with Argentina, Australia, and Brazil on satisfactory alternative means to address the threatened impairment to our national security posed by aluminum articles imported from these countries. I have determined that the necessary and appropriate means to address the threat to national security posed by imports of aluminum articles from Argentina, Australia, and Brazil is to extend the temporary exemption of these countries from the tariff proclaimed in Proclamation 9704, in order to finalize the details of these satisfactory alternative means to address the threatened impairment to our national security posed by aluminum articles imported from these countries. In my judgment, and

for the reasons I stated in paragraph 10 of Proclamation 9710, these discussions will be most productive if aluminum articles from Argentina, Australia, and Brazil remain exempt from the tariff proclaimed in Proclamation 9704, until the details can be finalized and implemented by proclamation. Because the United States has agreed in principle with these countries, in my judgment, it is unnecessary to set an expiration date for the exemptions. Nevertheless, if the satisfactory alternative means are not finalized shortly, I will consider re-imposing the tariff.

5. The United States is continuing discussions with Canada, Mexico, and the EU. I have determined that the necessary and appropriate means to address the threat to the national security posed by imports of aluminum articles from these countries is to continue these discussions and to extend the temporary exemption of these countries from the tariff proclaimed in Proclamation 9704, at least at this time. In my judgment, and for the reasons I stated in paragraph 10 of Proclamation 9710, these discussions will be most productive if aluminum articles from these countries remain exempt from the tariff proclaimed in Proclamation 9704.

6. For the reasons I stated in paragraph 11 of Proclamation 9710, however, the tariff imposed by Proclamation 9704 remains an important first step in ensuring the economic stability of our domestic aluminum industry and removing the threatened impairment of the national security. As a result, unless I determine by further proclamation that the United States has reached a satisfactory alternative means to remove the threatened impairment to the national security by imports of aluminum articles from Canada, Mexico, and the member countries of the EU, the tariff set forth in clause 2 of Proclamation 9704 shall be effective June 1, 2018, for these countries.

7. I have determined that, in light of the ongoing discussions that may result in long-term exclusions from the tariff proclaimed in Proclamation 9704, it is necessary and appropriate, at this time, to maintain the current tariff level as it applies to other countries.

8. Section 232 of the Trade Expansion Act of 1962, as amended, authorizes the President to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.

9. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (HTSUS) the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States of America, including section 232 of the Trade Expansion Act of 1962, as amended, section 301 of title 3, United States Code, and section 604 of the Trade Act of 1974, as amended, do hereby proclaim as follows:

(1) Imports of all aluminum articles from Argentina, Australia, and Brazil shall be exempt from the duty established in clause 2 of Proclamation 9704, as amended by clause 1 of Proclamation 9710. Imports of all aluminum articles from Canada, Mexico, and the member countries of the EU shall be exempt from the duty established in clause 2 of Proclamation 9704 until 12:01 a.m. eastern daylight time on June 1, 2018. Further, clause 2 of Proclamation 9704, as amended by clause 1 of Proclamation 9710, is also amended by striking the last two sentences and inserting in lieu thereof the following two sentences: ''Except as otherwise provided in this proclamation, or in notices published pursuant to clause 3 of this proclamation, all aluminum articles imports specified in the Annex shall be subject to an additional 10 percent ad valorem rate of duty with respect to goods entered for consumption, or withdrawn from warehouse for consumption, as follows: (a) on or after 12:01 a.m. eastern daylight time on March 23, 2018, from all countries except Argentina, Australia, Brazil, Canada, Mexico,

South Korea, and the member countries of the European Union, (b) on or after 12:01 a.m. eastern daylight time on May 1, 2018, from all countries except Argentina, Australia, Brazil, Canada, Mexico, and the member countries of the European Union, and (c) on or after 12:01 a.m. eastern daylight time on June 1, 2018, from all countries except Argentina, Australia, and Brazil. This rate of duty, which is in addition to any other duties, fees, exactions, and charges applicable to such imported aluminum articles, shall apply to imports of aluminum articles from each country as specified in the preceding sentence.''

(2) The exemption afforded to aluminum articles from Canada, Mexico, and the member countries of the EU shall apply only to aluminum articles of such countries entered for consumption, or withdrawn from warehouse for consumption, through the close of May 31, 2018, at which time such countries shall be deleted from the article description of heading 9903.85.01 of the HTSUS.

(3) Clause 5 of Proclamation 9710 is amended by inserting the phrase '', except those eligible for admission under ''domestic status'' as defined in 19 CFR 146.43, which is subject to the duty imposed pursuant to Proclamation 9704, as amended by Proclamation 9710,'' after the words ''Any aluminum article'' in the first and second sentences.

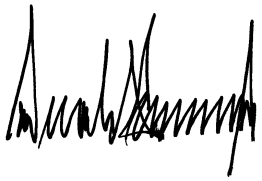
(4) Aluminum articles shall not be subject upon entry for consumption to the duty established in clause 2 of Proclamation 9704, as amended by clause 1 of this proclamation, merely by reason of manufacture in a U.S. foreign trade zone. However, aluminum articles admitted to a U.S. foreign trade zone in ''privileged foreign status'' pursuant to clause 5 of Proclamation 9710, as amended by clause 3 of this proclamation, shall retain that status consistent with 19 CFR 146.41(e).

(5) No drawback shall be available with respect to the duties imposed on any aluminum article pursuant to Proclamation 9704, as amended by clause 1 of this proclamation.

(6) The Secretary, in consultation with U.S. Customs and Border Protection of the Department of Homeland Security and other relevant executive departments and agencies, shall revise the HTSUS so that it conforms to the amendments and effective dates directed in this proclamation. The Secretary shall publish any such modification to the HTSUS in the *Federal Register.*

(7) Any provision of previous proclamations and Executive Orders that is inconsistent with the actions taken in this proclamation is superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-second.



Billing code 3295–F8–P

ANNEX

TO MODIFY CERTAIN PROVISIONS OF CHAPTER 99 OF THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

A. Subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTS) is modified as set forth below, with the material in the new tariff provisions inserted in the columns labeled "Heading/Subheading", "Article Description", "Rates of Duty 1-General", "Rates of Duty 1-Special," and "Rates of Duty 2", respectively. The modifications made in item 3 of this part shall be effective for goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on May 1, 2018. The modifications made in item 1 to subdivision (a) of U.S. note 19, as well as the modifications made in item 2 of this part, shall be effective for goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on March 23, 2018.

1. The text of subdivision (a) of U.S. note 19 to such subchapter is modified to read as follows:

"This note and the tariff provisions referred to herein set forth the ordinary customs duty treatment applicable to all entries of the aluminum products of all countries other than of the United States, when such aluminum products are classifiable in the headings or subheadings enumerated in subdivision (b) of this note. All anti-dumping or countervailing duties, or other duties and charges applicable to such goods shall continue to be imposed, except as may be expressly provided herein.

(i) Heading 9903.85.01 provides the ordinary customs duty treatment of aluminum products of all countries other than products of the United States and other than of countries expressly exempt therefrom, pursuant to the article description of such heading. For any such products that are eligible for special tariff treatment under any of the free trade agreements or preference programs listed in general note 3(c)(i) to the tariff schedule, the duty provided in this heading shall be collected in addition to any special rate of duty otherwise applicable under the appropriate tariff subheading, except where prohibited by law. Goods for which entry is claimed under a provision of chapter 98 and which are subject to the additional duties prescribed herein shall be eligible for and subject to the terms of such provision and applicable U.S. Customs and Border Protection ("CBP") regulations, except that duties under subheading 9802.00.60 shall be assessed based upon the full value of the imported article. No claim for entry or for any duty exemption or reduction shall be allowed for the aluminum products enumerated in subdivision (b) of this note under a provision of chapter 99 that may set forth a lower rate of duty or provide duty-free treatment, taking into account information supplied by CBP, but any additional duty prescribed in any provision of this subchapter or subchapter IV of chapter 99 shall be imposed in addition to the duty in heading 9903.85.01.

2. The text of subdivision (b) of U.S. note 19 is modified by adding below clause (b)(v) the sentence "Any reference above to aluminum products classifiable in any heading or subheading of chapter 76, as the case may be, shall mean that any good provided for in the article description of such heading or subheading and of all its subordinate provisions (both legal and statistical) is covered by the provisions of this note and related tariff provisions."

3. The following new subheadings and superior text thereto are inserted in numerical sequence in subchapter III:

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.85.01	Products of aluminum provided for in the tariff headings or subheadings enumerated in note 19 to this subchapter, except products of Argentina, of Australia, of Brazil, of Canada, of Mexico, or of the member countries of the European Union or any exclusions that may be determined and announced by the Department of Commerce.....	The duty provided in the applic-able subhe-ading + 10%	The duty provided in the applicable subheading + 10% (AU, BH, CA, CL, CO, E, IL, JO, KR, MA, MX, OM, P, PA, PE, SG)	The duty provided in the applica-ble subhe-ading + 10%

[FR Doc. 2018–09840

Filed 5–4–18; 11:15 a.m.]

Billing code 7020–02–C

Presidential Documents

Proclamation 9740 of April 30, 2018

Adjusting Imports of Steel Into the United States

By the President of the United States of America

A Proclamation

1. On January 11, 2018, the Secretary of Commerce (Secretary) transmitted to me a report on his investigation into the effect of imports of steel mill articles on the national security of the United States under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862).

2. In Proclamation 9705 of March 8, 2018 (Adjusting Imports of Steel Into the United States), I concurred in the Secretary's finding that steel mill articles are being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States, and decided to adjust the imports of steel mill articles, as defined in clause 1 of Proclamation 9705, as amended by clause 8 of Proclamation 9711 of March 22, 2018 (Adjusting Imports of Steel Into the United States) (steel articles), by imposing a 25 percent ad valorem tariff on such articles imported from all countries except Canada and Mexico. I further stated that any country with which we have a security relationship is welcome to discuss with the United States alternative ways to address the threatened impairment of the national security caused by imports from that country, and noted that, should the United States and any such country arrive at a satisfactory alternative means to address the threat to the national security such that I determine that imports from that country no longer threaten to impair the national security, I may remove or modify the restriction on steel articles imports from that country and, if necessary, adjust the tariff as it applies to other countries, as the national security interests of the United States require.

3. In Proclamation 9711, I noted the continuing discussions with the Argentine Republic (Argentina), the Commonwealth of Australia (Australia), the Federative Republic of Brazil (Brazil), Canada, Mexico, the Republic of Korea (South Korea), and the European Union (EU) on behalf of its member countries, on satisfactory alternative means to address the threatened impairment to the national security by imports of steel articles from those countries. Recognizing that each of these countries and the EU has an important security relationship with the United States, I determined that the necessary and appropriate means to address the threat to national security posed by imports of steel articles from these countries was to continue the ongoing discussions and to exempt steel articles imports from these countries from the tariff proclaimed in Proclamation 9705 until May 1, 2018.

4. The United States has successfully concluded discussions with South Korea on satisfactory alternative means to address the threatened impairment to our national security posed by steel articles imports from South Korea. The United States and South Korea have agreed on a range of measures, including measures to reduce excess steel production and excess steel capacity, and measures that will contribute to increased capacity utilization in the United States, including a quota that restricts the quantity of steel articles imported into the United States from South Korea. In my judgment, these measures will provide an effective, long-term alternative means to address South Korea's contribution to the threatened impairment to our national security by restraining steel articles exports to the United States

from South Korea, limiting transshipment, and discouraging excess capacity and excess steel production. In light of this agreement, I have determined that steel articles imports from South Korea will no longer threaten to impair the national security and have decided to exclude South Korea from the tariff proclaimed in Proclamation 9705. The United States will monitor the implementation and effectiveness of the quota and other measures agreed upon with South Korea in addressing our national security needs, and I may revisit this determination, as appropriate.

5. The United States has agreed in principle with Argentina, Australia, and Brazil on satisfactory alternative means to address the threatened impairment to our national security posed by steel articles imported from these countries. I have determined that the necessary and appropriate means to address the threat to national security posed by imports of steel articles from Argentina, Australia, and Brazil is to extend the temporary exemption of these countries from the tariff proclaimed in Proclamation 9705, in order to finalize the details of these satisfactory alternative means to address the threatened impairment to our national security posed by steel articles imported from these countries. In my judgment, and for the reasons I stated in paragraph 10 of Proclamation 9711, these discussions will be most productive if steel articles from Argentina, Australia, and Brazil remain exempt from the tariff proclaimed in Proclamation 9705, until the details can be finalized and implemented by proclamation. Because the United States has agreed in principle with these countries, in my judgment, it is unnecessary to set an expiration date for the exemptions. Nevertheless, if the satisfactory alternative means are not finalized shortly, I will consider re-imposing the tariff.

6. The United States is continuing discussions with Canada, Mexico, and the EU. I have determined that the necessary and appropriate means to address the threat to the national security posed by imports of steel articles from these countries is to continue these discussions and to extend the temporary exemption of these countries from the tariff proclaimed in Proclamation 9705, at least at this time. In my judgment, and for the reasons I stated in paragraph 10 of Proclamation 9711, these discussions will be most productive if steel articles from these countries remain exempt from the tariff proclaimed in Proclamation 9705.

7. For the reasons I stated in paragraph 11 of Proclamation 9711, however, the tariff imposed by Proclamation 9705 remains an important first step in ensuring the economic stability of our domestic steel industry and removing the threatened impairment of the national security. As a result, unless I determine by further proclamation that the United States has reached a satisfactory alternative means to remove the threatened impairment to the national security by imports of steel articles from Canada, Mexico, and the member countries of the EU, the tariff set forth in clause 2 of Proclamation 9705 shall be effective June 1, 2018, for these countries.

8. In light of my determination to exclude, on a long-term basis, South Korea from the tariff proclaimed in Proclamation 9705, I have considered whether it is necessary and appropriate in light of our national security interests to make any corresponding adjustments to the tariff set forth in clause 2 of Proclamation 9705 as it applies to other countries. I have determined that, in light of the agreed-upon quota and other measures with South Korea, the measures being finalized with Argentina, Australia, and Brazil, and the ongoing discussions that may result in further long-term exclusions from the tariff proclaimed in Proclamation 9705, it is necessary and appropriate, at this time, to maintain the current tariff level as it applies to other countries.

9. Section 232 of the Trade Expansion Act of 1962, as amended, authorizes the President to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.

10. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483), authorizes the President to embody in the Harmonized Tariff Schedule of the United States (HTSUS) the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States of America, including section 232 of the Trade Expansion Act of 1962, as amended, section 301 of title 3, United States Code, and section 604 of the Trade Act of 1974, as amended, do hereby proclaim as follows:

(1) Imports of all steel articles from Argentina, Australia, Brazil, and South Korea shall be exempt from the duty established in clause 2 of Proclamation 9705, as amended by clause 1 of Proclamation 9711. Imports of all steel articles from Canada, Mexico, and the member countries of the EU shall be exempt from the duty established in clause 2 of Proclamation 9705 until 12:01 a.m. eastern daylight time on June 1, 2018. Further, clause 2 of Proclamation 9705, as amended by clause 1 of Proclamation 9711, is also amended by striking the last two sentences and inserting in lieu thereof the following two sentences: ''Except as otherwise provided in this proclamation, or in notices published pursuant to clause 3 of this proclamation, all steel articles imports specified in the Annex shall be subject to an additional 25 percent ad valorem rate of duty with respect to goods entered for consumption, or withdrawn from warehouse for consumption, as follows: (a) on or after 12:01 a.m. eastern daylight time on March 23, 2018, from all countries except Argentina, Australia, Brazil, Canada, Mexico, South Korea, and the member countries of the European Union, and (b) on or after 12:01 a.m. eastern daylight time on June 1, 2018, from all countries except Argentina, Australia, Brazil, and South Korea. This rate of duty, which is in addition to any other duties, fees, exactions, and charges applicable to such imported steel articles, shall apply to imports of steel articles from each country as specified in the preceding sentence.''.

(2) In order to provide the quota treatment referred to in paragraph 4 of this proclamation to steel articles imports from South Korea, U.S. Note 16 of subchapter III of chapter 99 of the HTSUS is amended as provided for in Part A of the Annex to this proclamation. U.S. Customs and Border Protection (CBP) of the Department of Homeland Security shall implement this quota as soon as practicable, taking into account all steel articles imports from South Korea since January 1, 2018.

(3) The exemption afforded to steel articles from Canada, Mexico, and the member countries of the EU shall apply only to steel articles of such countries entered for consumption, or withdrawn from warehouse for consumption, through the close of May 31, 2018, at which time such countries shall be deleted from the article description of heading 9903.80.01 of the HTSUS.

(4) Clause 5 of Proclamation 9711 is amended by inserting the phrase '', except those eligible for admission under ''domestic status'' as defined in 19 CFR 146.43, which is subject to the duty imposed pursuant to Proclamation 9705, as amended by Proclamation 9711,'' after the words ''Any steel article'' in the first and second sentences.

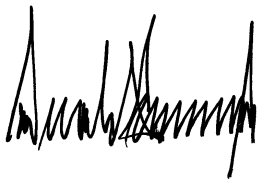
(5) Steel articles shall not be subject upon entry for consumption to the duty established in clause 2 of Proclamation 9705, as amended by clause 1 of this proclamation, merely by reason of manufacture in a U.S. foreign trade zone. However, steel articles admitted to a U.S. foreign trade zone in ''privileged foreign status'' pursuant to clause 5 of Proclamation 9711, as amended by clause 4 of this proclamation, shall retain that status consistent with 19 CFR 146.41(e).

(6) No drawback shall be available with respect to the duties imposed on any steel article pursuant to Proclamation 9705, as amended by clause 1 of this proclamation.

(7) The Secretary, in consultation with CBP and other relevant executive departments and agencies, shall revise the HTSUS so that it conforms to the amendments and effective dates directed in this proclamation. The Secretary shall publish any such modification to the HTSUS in the *Federal Register*.

(8) Any provision of previous proclamations and Executive Orders that is inconsistent with the actions taken in this proclamation is superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of April, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-second.



Billing code 3295–F8–P

ANNEX

TO MODIFY CERTAIN PROVISIONS OF CHAPTER 99 OF THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

A. Subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTS) is modified below, with the material in the new tariff provisions inserted in the columns labeled "Heading/Subheading", "Article Description", "Rates of Duty 1-General", "Rates of Duty 1-Special," and "Rates of Duty 2", respectively. Except as provided in the superior text to subheadings 9903.80.05 through 9903.80.58 in item 4, the modifications made in items 1, 3 and 4 of this part shall be effective for goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on May 1, 2018; except that the modifications in item 1 to the opening paragraph of subdivision (a) and to subdivision (a)(i) of U.S. note 16, as well as the modifications made in item 2 of this part, shall be effective for goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on March 23, 2018. Quota amounts are calculated beginning on January 1 of each calendar year, including for calendar year 2018.

1. The text of subdivision (a) of U.S. note 16 to such subchapter is modified to read as follows:

> "This note and the tariff provisions referred to herein set forth the ordinary customs duty treatment applicable to all entries of the iron or steel products of all countries other than of the United States, when such iron or steel products are classifiable in the headings or subheadings enumerated in subdivision (b) of this note. All anti-dumping or countervailing duties, or other duties and charges applicable to such goods shall continue to be imposed, except as may be expressly provided herein.
>
> (i) Heading 9903.80.01 provides the ordinary customs duty treatment of iron or steel products of all countries other than products of the United States and other than of countries expressly exempt therefrom, pursuant to the article description of such heading and the terms of subdivision (e) of this note. For any such products that are eligible for special tariff treatment under any of the free trade agreements or preference programs listed in general note 3(c)(i) to the tariff schedule, the duty provided in this heading shall be collected in addition to any special rate of duty otherwise applicable under the appropriate tariff subheading, except where prohibited by law. Goods for which entry is claimed under a provision of chapter 98 and which are subject to the additional duties prescribed herein shall be eligible for and subject to the terms of such provision and applicable U.S. Customs and Border Protection ("CBP") regulations, except that duties under subheading 9802.00.60 shall be assessed based upon the full value of the imported article. No claim for entry or for any duty exemption or reduction shall be allowed for the iron or steel products enumerated in subdivision (b) of this note under a provision of chapter 99 that may set forth a lower rate of duty or provide duty-free treatment, taking into account information supplied by CBP, but any additional duty prescribed in any provision of this subchapter or subchapter IV of chapter 99 shall be imposed in addition to the duty in heading 9903.80.01.

(ii) Subheadings 9903.80.05 through 9903.80.58, inclusive, provide the ordinary customs duty and quota treatment of such goods enumerated in subdivision (b) of this note when they are the product of any country enumerated in the superior text thereto and expressly exempt from the scope of heading 9903.80.01, subject to the limitations in subdivision (e) of this note.

2. The text of subdivision (b) of such U.S. note 16 is modified by adding below clause (b)(v) the sentence "Any reference above to iron or steel products classifiable in any heading or subheading of chapter 72 or 73, as the case may be, shall mean that any good provided for in the article description of such heading or subheading and of all its subordinate provisions (both legal and statistical) is covered by the provisions of this note and related tariff provisions." The text of subdivisions (b), (c) and (d) of such U.S. note 16 are each modified by deleting "heading 9903.80.01" and by inserting in lieu thereof "heading 9903.80.01 and subheadings 9903.80.05 through 9903.80.58, inclusive,".

3. The following new subdivision (e) is hereby inserted at the end of such U.S. note 16:

"(e) Subheadings 9903.80.05 through 9903.80.58, inclusive, set forth the ordinary customs duty treatment for the iron or steel products (as enumerated in subdivision (b) of this note) of any country enumerated in the superior text to such subheadings, subject to the annual aggregate quantitative limitations proclaimed for these subheadings and as set forth on the Internet site of CBP at the following link: https://www.cbp.gov/trade/quota . Imports from any such country in an aggregate quantity under any such subheading during any of the periods January through March, April through June, July through September, or October through December in any year that is in excess of 30 percent of the total aggregate quantity provided for a calendar year for such country, as set forth on the Internet site of CBP, shall not be allowed."

4. The following new subheadings and superior text thereto are inserted in numerical sequence in subchapter III:

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
	Iron or steel products of South Korea enumerated in U.S. note 16(b) to this subchapter, if entered in aggregate quantities prescribed in subdivision (e) of such note for any calendar year starting on January 1, 2018 and for any portion thereof as prescribed in such subdivision (e):			
9903.80.05	Hot-rolled sheet, provided for in subheading 7208.10.60, 7208.26.00, 7208.27.00, 7208.38.00, 7208.39.00, 7208.40.60, 7208.53.00, 7208.54.00, 7208.90.00, 7225.30.70 or 7225.40.70	Free		
9903.80.06	Hot-rolled strip, provided for in subheading 7211.19.15, 7211.19.20, 7211.19.30, 7211.19.45, 7211.19.60, 7211.19.75, 7226.91.70 or 7226.91.80	Free		
9903.80.07	Hot-rolled plate, in coils, provided for in subheading 7208.10.15, 7208.10.30, 7208.25.30, 7208.25.60, 7208.36.00, 7208.37.00, 7211.14.00 (except for statistical reporting numbers 7211.14.0030 and 7211.14.0045) or 7225.30.30	Free		
9903.80.08	Cold-rolled sheet and other products, provided for in subheading 7209.15.00, 7209.16.00, 7209.17.00, 7209.18.15, 7209.18.60, 7209.25.00, 7209.26.00, 7209.27.00, 7209.28.00, 7209.90.00, 7210.70.30, 7225.50.70, 7225.50.80 or 7225.99.00	Free		
9903.80.09	Cold-rolled strip and other products, provided for in subheading 7211.23.15, 7211.23.20, 7211.23.30, 7211.23.45, 7211.23.60, 7211.29.20, 7211.29.45, 7211.29.60, 7211.90.00, 7212.40.10, 7212.40.50, 7226.92.50, 7226.92.70, 7226.92.80 or 7226.99.01 (except for statistical reporting numbers 7226.99.0110 and 7226.99.0130)	Free		
9903.80.10	Cold-rolled black plate, provided for in subheading 7209.18.25	Free		
9903.80.11	Plate in cut lengths, provided for in subheading 7208.40.30, 7208.51.00, 7208.52.00, 7210.90.10, 7211.13.00, 7211.14.00 (except for statistical reporting number 7211.14.0090), 7225.40.30, 7225.50.60 or 7226.91.50	Free		

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.80.12	Flat-rolled products, hot-dipped, provided for in subheading 7210.41.00, 7210.49.00, 7210.70.60 (except for statistical reporting numbers 7210.70.6030 and 7210.70.6090), 7212.30.10, 7212.30.30, 7212.30.50, 7225.92.00 or 7226.99.01 (except for statistical reporting numbers 7226.99.0110 and 7226.99.0180)	Free		
9903.80.13	Flat-rolled products, coated, provided for in subheading 7210.20.00, 7210.61.00, 7210.69.00, 7210.70.60 (except for statistical reporting numbers 7210.70.6030 and 7210.70.6060), 7210.90.60, 7210.90.90, 7212.50.00 or 7212.60.00	Free		
9903.80.14	Tin-free steel, provided for in subheading 7210.50.00	Free		
9903.80.15	Tin plate, provided for in subheading 7210.11.00, 7210.12.00 or 7212.10.00	Free		
9903.80.16	Silicon electrical steel sheets and strip, provided for in subheading 7225.11.00, 7225.19.00, 7226.11.10, 7226.11.90, 7226.19.10 or 7226.19.90	Free		
9903.80.17	Sheets and strip electrolytically coated or plated with zinc, provided for in subheading 7210.30.00, 7210.70.60 (except for statistical reporting numbers 7210.70.6060 and 7210.70.6090), 7212.20.00, 7225.91.00 or 7226.99.01 (except for statistical reporting numbers 7226.99.0130 and 7226.99.0180)	Free		
9903.80.18	Oil country pipe and tube goods, provided for in subheading 7304.23.30, 7304.23.60, 7304.29.10, 7304.29.20, 7304.29.31, 7304.29.41, 7304.29.50, 7304.29.61, 7305.20.20, 7305.20.40, 7305.20.60, 7305.20.80, 7306.29.10, 7306.29.20, 7306.29.31, 7306.29.41, 7306.29.60 or 7306.29.81	Free		

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.80.19	Line pipe exceeding 406.4 mm in outside diameter, provided for in subheading 7304.19.10 (except for statistical reporting numbers 7304.19.1020, 7304.19.1030, 7304.19.1045 and 7304.19.1060), 7304.19.50 (except for statistical reporting numbers 7304.19.5020 and 7304.19.5050), 7305.11.10, 7305.11.50, 7305.12.10, 7305.12.50, 7305.19.10 or 7305.19.50	Free		
9903.80.20	Line pipe not exceeding 406.4 mm in outside diameter, provided for in subheading 7304.19.10 (except for statistical reporting number 7304.19.1080), 7304.19.50 (except for statistical reporting number 7304.19.5080), 7306.19.10 (except for statistical reporting number 7306.19.1050) or 7306.19.51 (except for statistical reporting number 7306.19.5150)	Free		
9903.80.21	Other line pipe, provided for in subheading 7306.19.10 (except for statistical reporting number 7306.19.1010) or 7306.19.51 (except for statistical reporting number 7306.19.5110)	Free		
9903.80.22	Standard pipe, provided for in subheading 7304.39.00 (except for statistical reporting numbers 7304.39.0002, 7304.39.0004, 7304.39.0006, 7304.39.0008, 7304.39.0028, 7304.39.0032, 7304.39.0040, 7304.39.0044, 7304.39.0052, 7304.39.0056, 7304.39.0068 and 7304.39.0072), 7304.59.80 (except for statistical reporting numbers 7304.59.8020, 7304.59.8025, 7304.59.8035, 7304.59.8040, 7304.59.8050, 7304.59.8055, 7304.59.8065 and 7304.59.8070) or 7306.30.50 (except for statistical reporting numbers 7306.30.5010, 7306.30.5015, 7306.30.5020 and 7306.30.5035)	Free		
9903.80.23	Structural pipe and tube, provided for in subheading 7304.90.10, 7304.90.30, 7305.31.20, 7305.31.40, 7305.31.60 (except for statistical reporting number 7305.31.6010), 7306.30.30, 7306.50.30, 7306.61.10, 7306.61.30, 7306.69.10 or 7306.69.30	Free		

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.80.24	Mechanical tubing and other products, provided for in subheading 7304.31.30, 7304.31.60 (except for statistical reporting number 7304.31.6010), 7304.39.00 (except for statistical reporting numbers 7304.39.0002, 7304.39.0004, 7304.39.0006, 7304.39.0008, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0036, 7304.39.0048, 7304.39.0062, 7304.39.0076 and 7304.39.0080), 7304.51.10, 7304.51.50 (except for statistical reporting numbers 7304.51.5005, 7304.51.5015 and 7304.51.5045), 7304.59.10, 7304.59.60, 7304.59.80 (except for statistical reporting numbers 7304.59.8010, 7304.59.8015, 7304.59.8030, 7304.59.8045, 7304.59.8060 and 7304.59.8080), 7304.90.50, 7304.90.70, 7306.30.10, 7306.30.50 (except for statistical reporting numbers 7306.30.5010, 7306.30.5025, 7306.30.5028, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085 and 7306.30.5090), 7306.50.10, 7306.50.50 (except for statistical reporting number 7306.50.5010), 7306.61.50, 7306.61.70 (except for statistical reporting number 7306.61.7030), 7306.69.50 or 7306.69.70 (except for statistical reporting number 7306.69.7030).....	Free		
9903.80.25	Pressure tubing and other products, provided for in subheading 7304.31.60 (except for statistical reporting number 7304.31.6050), 7304.39.00 (except for statistical reporting numbers 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076 and 7304.39.0080), 7304.51.50 (except for statistical reporting numbers 7304.51.5005 and 7304.51.5060), 7304.59.20, 7306.30.50 (except for statistical reporting numbers 7306.30.5015, 7306.30.5020, 7306.30.5025, 7306.30.5028, 7306.30.5032, 7306.30.5035, 7306.30.5040, 7306.30.5055, 7306.30.5085 and 7306.30.5090) or 7306.50.50 (except for statistical reporting numbers 7306.50.5030, 7306.50.5050 and 7306.50.5070).....	Free		

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.80.26	Tubes or pipes for piling and other products, provided for in subheading 7305.39.10 or 7305.39.50	Free		
9903.80.27	Pipes and tubes, not specially provided for, provided for in subheading 7304.51.50 (except for statistical reporting numbers 7304.51.5015, 7304.51.5045 and 7304.51.5060), 7305.90.10, 7305.90.50, 7306.90.10 or 7306.90.50	Free		
9903.80.28	Hot-rolled sheet of stainless steel, provided for in subheading 7219.13.00, 7219.14.00, 7319.23.00 or 7219.24.00	Free		
9903.80.29	Hot-rolled strip of stainless steel and other products, provided for in subheading 7220.12.10 or 7220.12.50	Free		
9903.80.30	Hot-rolled plate of stainless steel, in coils, and other products, provided for in subheading 7219.11.00 or 7219.12.00	Free		
9903.80.31	Cold-rolled sheet of stainless steel and other products, provided for in subheading 7219.32.00, 7219.33.00, 7219.34.00, 7219.35.00 or 7219.90.00	Free		
9903.80.32	Cold-rolled strip of stainless steel, provided for in subheading 7220.20.10, 7220.20.60, 7220.20.70, 7220.20.80, 7220.20.90 or 7220.90.00	Free		
9903.80.33	Cold-rolled plate of stainless steel, in coils, provided for in subheading 7219.31.00 (except for statistical reporting number 7219.31.0050)	Free		
9903.80.34	Wire of stainless steel, drawn, provided for in subheading 7223.00.10, 7223.00.50 or 7223.00.90	Free		
9903.80.35	Pipes and tubes of stainless steel, provided for in subheading 7304.41.30, 7304.41.60, 7304.49.00, 7305.31.60 (except for statistical reporting number 7305.31.6090), 7306.40.10, 7306.40.50, 7306.61.70 (except for statistical reporting number 7306.61.7060) or 7306.69.70 (except for statistical reporting number 7306.69.7060)	Free		
9903.80.36	Line pipe of stainless steel, provided for in subheading 7304.11.00 or 7306.11.00	Free		

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.80.37	Bars and rods of stainless steel, cold finished, provided for in subheading 7222.20.00 or 7222.30.00	Free		
9903.80.38	Bars and rods of stainless steel, hot-rolled, provided for in heading 7221.00.00 (except for statistical reporting numbers 7221.00.0017, 7221.00.0018 and 7221.00.0030) or subheading 7222.11.00, 7222.19.00 or 7222.40.30 (except for statistical reporting numbers 7222.40.3025 and 7222.40.3045)	Free		
9903.80.39	Blooms, billets and slabs of stainless steel and other products, provided for in subheading 7218.91.00 and 7218.99.00	Free		
9903.80.40	Oil country pipe and tube goods of stainless steel and other products, provided for in subheading 7304.22.00, 7304.24.30, 7304.24.40, 7304.24.60, 7306.21.30, 7306.21.40 or 7306.21.80	Free		
9903.80.41	Ingot and other primary forms of stainless steel, provided for in subheading 7218.10.00	Free		
9903.80.42	Flat-rolled products of stainless steel, provided for in subheading 7219.21.00, 7219.22.00, 7219.31.00 (except for statistical reporting number 7219.31.0010) or 7220.11.00	Free		
9903.80.43	Bars and rods, hot-rolled, in irregularly wound coils, of stainless steel, provided for in heading 7221.00.00 (except for statistical reporting numbers 7221.00.0005, 7221.00.0045 and 7221.00.0075)	Free		
9903.80.44	Angles, shapes and sections of stainless steel, provided for in subheading 7222.40.30 (except for statistical reporting numbers 7222.40.3065 and 7222.40.3085) or 7222.40.60	Free		
9903.80.45	Angles, shapes and sections, provided for in subheading 7216.31.00, 7216.32.00, 7216.33.00, 7216.40.00, 7216.50.00, 7216.99.00, 7228.70.30 (except for statistical reporting numbers 7228.70.3060 and 7228.70.3081) or 7228.70.60	Free		

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
9903.80.46	Bars and rods, hot-rolled, in irregularly wound coils, provided for in subheading 7213.91.30, 9213.91.45, 7213.91.60, 7213.99.00 (except for statistical reporting number 7213.99.0060), 7227.20.00 (except for statistical reporting number 7227.20.0080) or 7227.90.60 (except for statistical reporting numbers 7227.90.6005, 7227.90.6010, 7227.90.6040 and 7227.90.6090)	Free		
9903.80.47	Wire (other than of stainless steel), provided for in subheading 7217.10.10, 7217.10.20, 7217.10.30, 7217.10.40, 7217.10.50, 7217.10.60, 7217.10.70, 7217.10.80, 7217.10.90, 7217.20.15, 7217.20.30, 7217.20.45, 7217.20.60, 7217.20.75, 7217.30.15, 7217.30.30, 7217.30.45, 7217.30.60, 7217.30.75, 7217.90.10, 7217.90.50, 7229.20.00, 7229.90.10, 7229.90.50 or 7229.90.90	Free		
9903.80.48	Bars, hot-rolled, not of stainless steel, provided for in subheading 7213.20.00, 7213.99.00 (except for statistical reporting numbers 7213.99.0030 and 7213.99.0090), 7214.10.00, 7214.30.00, 7214.91.00, 7214.99.00, 7215.90.10, 7227.20.00 (except for statistical reporting number 7227.20.0030), 7227.90.60 (except for statistical reporting numbers 7227.90.6020, 7227.90.6030 and 7227.90.6035), 7228.20.10, 7228.30.80 (except for statistical reporting number 7228.30.8010), 7228.40.00, 7228.60.60 or 7228.80.00	Free		
9903.80.49	Bars, cold-finished, not of stainless steel, provided for in subheading 7215.10.00, 7215.50.00, 7215.90.30, 7215.90.50, 7228.20.50, 7228.50.50 or 7228.60.80	Free		
9903.80.50	Angles, shapes and sections of a type known as "light-shaped bars" and other products, provided for in subheading 7216.10.00, 7216.21.00, 7216.22.00 or 7228.70.30 (except for statistical reporting numbers 7228.70.3010, 7228.70.3020 and 7228.70.3041)	Free		
9903.80.51	Reinforcing bars, provided for in subheading 7213.10.00, 7214.20.00 or 7228.30.80 (except for			

Heading/ Subheading	Article description	Rates of Duty		
		1		2
		General	Special	
	statistical reporting numbers 7228.30.8005, 7228.30.8015, 7228.30.8041, 7228.30.8045 and 7228.30.8070)	Free		
9903.80.52	Sheet piling, provided for in subheading 7301.10.00	Free		
9903.80.53	Nonumerated railroad goods, provided for in subheading 7302.40.00, 7302.90.10 and 7302.90.90	Free		
9903.80.54	Rails other than those known as "standard rails," provided for in subheading 7302.10.10 (except for statistical reporting numbers 7302.10.1010, 7302.10.1035, 7302.10.1065 and 7302.10.1075)	Free		
9903.80.55	Rails known as "standard rails," provided for in subheading 7302.10.10 (except for statistical reporting numbers 7302.10.1015, 7302.10.1025, 7302.10.1045 and 7302.10.1055) or 7302.10.50	Free		
9903.80.56	Products of tool steel and other products, provided for in subheading 7224.10.00 (except for statistical reporting numbers 7224.10.0005 and 7224.10.0075), 7224.90.00 (except for statistical reporting numbers 7224.90.0005, 7224.90.0045, 7224.90.0055, 7224.90.0065 and 7224.90.0075), 7225.30.11, 7225.30.51, 7225.40.11, 7225.40.51, 7225.50.11, 7226.20.00, 7226.91.05, 7226.91.15, 7226.91.25, 7226.92.10, 7226.92.30, 7227.10.00, 7227.90.10, 7227.90.20, 7228.10.00, 7228.30.20, 7228.30.40, 7228.30.60, 7228.50.10, 7228.60.10 or 7229.90.05	Free		
9903.80.57	Blooms, billets and slabs, semi-finished, provided for in subheading 7207.11.00, 7207.12.00, 7207.19.00, 7207.20.00 or 7224.90.00 (except for statistical reporting numbers 7224.90.0015, 7224.90.0025, and 7224.90.0035)	Free		
9903.80.58	Ingots, provided for in subheading 7206.10.00, 7206.90.00 or 7224.10.00 (except for statistical reporting number 7224.10.0045)	Free		

B. For the purposes of administering the quantitative limitations applicable to subheadings 9903.80.05 through 9903.80.58 (as created in part A of this annex), the following annual aggregate limits shall apply for the period starting with calendar year 2018 and for subsequent years, unless modified or terminated:

SOUTH KOREA

Heading/ Subheading	Article description	Quantitative Limitation
	Iron or steel products of South Korea enumerated in U.S. note 16(b) to this subchapter, if entered in aggregate quantities prescribed in subdivision (e) of such note for any calendar year starting on January 1, 2018 and for any portion thereof as prescribed in such subdivision (e):	
9903.80.05	Hot-rolled sheet, provided for in subheading 7208.10.60, 7208.26.00, 7208.27.00, 7208.38.00, 7208.39.00, 7208.40.60, 7208.53.00, 7208.54.00, 7208.90.00, 7225.30.70 or 7225.40.70	404,694,045 kg
9903.80.06	Hot-rolled strip, provided for in subheading 7211.19.15, 7211.19.20, 7211.19.30, 7211.19.45, 7211.19.60, 7211.19.75, 7226.91.70 or 7226.91.80	249,173 kg
9903.80.07	Hot-rolled plate, in coils, provided for in subheading 7208.10.15, 7208.10.30, 7208.25.30, 7208.25.60, 7208.36.00, 7208.37.00, 7211.14.00 (except for statistical reporting numbers 7211.14.0030 and 7211.14.0045) or 7225.30.30	125,346,920 kg
9903.80.08	Cold-rolled sheet, and other products, provided for in subheading 7209.15.00, 7209.16.00, 7209.17.00, 7209.18.15, 7209.18.60, 7209.25.00, 7209.26.00, 7209.27.00, 7209.28.00, 7209.90.00, 7210.70.30, 7225.50.70, 7225.50.80 or 7225.99.00	90,336,230 kg
9903.80.09	Cold-rolled strip, and other products, provided for in subheading 7211.23.15, 7211.23.20, 7211.23.30, 7211.23.45, 7211.23.60, 7211.29.20, 7211.29.45, 7211.29.60, 7211.90.00, 7212.40.10, 7212.40.50, 7226.92.50, 7226.92.70, 7226.92.80 or 7226.99.01 (except for statistical reporting numbers 7226.99.0110 and 7226.99.0130)	3,207,110 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.10	Cold-rolled black plate, provided for in subheading 7209.18.25	34,385,821 kg
9903.80.11	Plate in cut lengths, provided for in subheading 7208.40.30, 7208.51.00, 7208.52.00, 7210.90.10, 7211.13.00, 7211.14.00 (except for statistical reporting number 7211.14.0090), 7225.40.30, 7225.50.60 or 7226.91.50	202,530,628 kg
9903.80.12	Flat-rolled products, hot-dipped, provided for in subheading 7210.41.00, 7210.49.00, 7210.70.60 (except for statistical reporting numbers 7210.70.6030 and 7210.70.6090), 7212.30.10, 7212.30.30, 7212.30.50, 7225.92.00 or 7226.99.01 (except for statistical reporting numbers 7226.99.0110 and 7226.99.0180)	166,310,597 kg
9903.80.13	Flat-rolled products, coated, provided for in subheading 7210.20.00, 7210.61.00, 7210.69.00, 7210.70.60 (except for statistical reporting numbers 7210.70.6030 and 7210.70.6060), 7210.90.60, 7210.90.90, 7212.50.00 or 7212.60.00	190,840,544 kg
9903.80.14	Tin-free steel, provided for in subheading 7210.50.00	18,374,353 kg
9903.80.15	Tin plate, provided for in subheading 7210.11.00, 7210.12.00 or 7212.10.00	54,749,093 kg
9903.80.16	Silicon electrical steel sheets and strip, provided for in subheading 7225.11.00, 7225.19.00, 7226.11.10, 7226.11.90, 7226.19.10 or 7226.19.90	7,505,976 kg
9903.80.17	Sheets and strip electrolytically coated or plated with zinc, provided for in subheading 7210.30.00, 7210.70.60 (except for statistical reporting numbers 7210.70.6060 and 7210.70.6090), 7212.20.00, 7225.91.00 or 7226.99.01 (except for statistical reporting numbers 7226.99.0130 and 7226.99.0180)	13,094,743 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.18	Oil country pipe and tube goods, provided for in subheading 7304.23.30, 7304.23.60, 7304.29.10, 7304.29.20, 7304.29.31, 7304.29.41, 7304.29.50, 7304.29.61, 7305.20.20, 7305.20.40, 7305.20.60, 7305.20.80, 7306.29.10, 7306.29.20, 7306.29.31, 7306.29.41, 7306.29.60 or 7306.29.81	460,867,818 kg
9903.80.19	Line pipe exceeding 406.4 mm in outside diameter, provided for in subheading 7304.19.10 (except for statistical reporting numbers 7304.19.1020, 7304.19.1030, 7304.19.1045 and 7304.19.1060), 7304.19.50 (except for statistical reporting numbers 7304.19.5020 and 7304.19.5050), 7305.11.10, 7305.11.50, 7305.12.10, 7305.12.50, 7305.19.10 or 7305.19.50	125,646,499 kg
9903.80.20	Line pipe not exceeding 406.4 mm in outside diameter, provided for in subheading 7304.19.10 (except for statistical reporting number 7304.19.1080), 7304.19.50 (except for statistical reporting number 7304.19.5080), 7306.19.10 (except for statistical reporting number 7306.19.1050) or 7306.19.51 (except for statistical reporting number 7306.19.5150)	51,383,847 kg
9903.80.21	Other line pipe, provided for in subheading 7306.19.10 (except for statistical reporting number 7306.19.1010) or 7306.19.51 (except for statistical reporting number 7306.19.5110)	250,007,048 kg
9903.80.22	Standard pipe, provided for in subheading 7304.39.00 (except for statistical reporting numbers 7304.39.0002, 7304.39.0004, 7304.39.0006, 7304.39.0008, 7304.39.0028, 7304.39.0032, 7304.39.0040, 7304.39.0044, 7304.39.0052, 7304.39.0056, 7304.39.0068 and 7304.39.0072), 7304.59.80 (except for statistical reporting numbers 7304.59.8020, 7304.59.8025, 7304.59.8035, 7304.59.8040, 7304.59.8050, 7304.59.8055, 7304.59.8065 and 7304.59.8070) or 7306.30.50 (except for statistical reporting numbers 7306.30.5010, 7306.30.5015, 7306.30.5020 and 7306.30.5035)	69,469,685 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.23	Structural pipe and tube, provided for in subheading 7304.90.10, 7304.90.30, 7305.31.20, 7305.31.40, 7305.31.60 (except for statistical reporting number 7305.31.6010), 7306.30.30, 7306.50.30, 7306.61.10, 7306.61.30, 7306.69.10 or 7306.69.30.....	54,003,708 kg
9903.80.24	Mechanical tubing and other products, provided for in subheading 7304.31.30, 7304.31.60 (except for statistical reporting numbers 7304.31.6010), 7304.39.00 (except for statistical reporting numbers 7304.39.0002, 7304.39.0004, 7304.39.0006, 7304.39.0008, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0036, 7304.39.0048, 7304.39.0062, 7304.39.0076 and 7304.39.0080), 7304.51.10, 7304.51.50 (except for statistical reporting numbers 7304.51.5005, 7304.51.5015 and 7304.51.5045), 7304.59.10, 7304.59.60, 7304.59.80 (except for statistical reporting numbers 7304.59.8010, 7304.59.8015, 7304.59.8030, 7304.59.8045, 7304.59.8060 and 7304.59.8080), 7304.90.50, 7304.90.70, 7306.30.10, 7306.30.50 (except for statistical reporting numbers 7306.30.5010, 7306.30.5025, 7306.30.5028, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085 and 7306.30.5090), 7306.50.10, 7306.50.50 (except for statistical reporting number 7306.50.5010), 7306.61.50, 7306.61.70 (except for statistical reporting number 7306.61.7030), 7306.69.50 or 7306.69.70 (except for statistical reporting number 7306.69.7030).....	8,438,050 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.25	Pressure tubing and other products, provided for in subheading 7304.31.60 (except for statistical reporting number 7304.31.6050), 7304.39.00 (except for statistical reporting numbers 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.39.0076 and 7304.39.0080), 7304.51.50 (except for statistical reporting numbers 7304.51.5005 and 7304.51.5060), 7304.59.20, 7306.30.50 (except for statistical reporting numbers 7306.30.5015, 7306.30.5020, 7306.30.5025, 7306.30.5028, 7306.30.5032, 7306.30.5035, 7306.30.5040, 7306.30.5055, 7306.30.5085 and 7306.30.5090) or 7306.50.50 (except for statistical reporting numbers 7306.50.5030, 7306.50.5050 and 7306.50.5070)	1,172,695 kg
9903.80.26	Tubes or pipes for piling and other products, provided for in subheading 7305.39.10 or 7305.39.50	4,807,122 kg
9903.80.27	Pipes and tubes, not specially provided for, provided for in subheading 7304.51.50 (except for statistical reporting numbers 7304.51.5015, 7304.51.5045 and 7304.51.5060), 7305.90.10, 7305.90.50, 7306.90.10 or 7306.90.50	449,740 kg
9903.80.28	Hot-rolled sheet of stainless steel, provided for in subheading 7219.13.00, 7219.14.00, 7319.23.00 or 7219.24.00	1,172,992 kg
9903.80.29	Hot-rolled strip of stainless steel and other products, provided for in subheading 7220.12.10 or 7220.12.50	13,346 kg
9903.80.30	Hot-rolled plate of stainless steel, in coils, and other products, provided for in subheading 7219.11.00 or 7219.12.00	218,649 kg
9903.80.31	Cold-rolled sheet of stainless steel and other products, provided for in subheading 7219.32.00, 7219.33.00, 7219.34.00, 7219.35.00 or 7219.90.00	13,460,008 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.32	Cold-rolled strip of stainless steel, provided for in subheading 7220.20.10, 7220.20.60, 7220.20.70, 7220.20.80, 7220.20.90 or 7220.90.00	1,649,722 kg
9903.80.33	Cold-rolled plate of stainless steel, in coils, provided for in subheading 7219.31.00 (except for statistical reporting number 7219.31.0050)	24,905 kg
9903.80.34	Wire of stainless steel, drawn, provided for in subheading 7223.00.10, 7223.00.50 or 7223.00.90	5,338,007 kg
9903.80.35	Pipes and tubes of stainless steel, provided for in subheading 7304.41.30, 7304.41.60, 7304.49.00, 7305.31.60 (except for statistical reporting number 7305.31.6090), 7306.40.10, 7306.40.50, 7306.61.70 (except 7306.61.7060) or 7306.69.70 (except for statistical reporting number 7306.69.7060)	12,602,387 kg
9903.80.36	Line pipe of stainless steel, provided for in subheading 7304.11.00 or 7306.11.00	1,254,097 kg
9903.80.37	Bars and rods of stainless steel, cold finished, provided for in subheading 7222.20.00 or 7222.30.00	224,622 kg
9903.80.38	Bars and rods of stainless steel, hot-rolled, provided for in heading 7221.00.00 (except for statistical reporting numbers 7221.00.0017, 7221.00.0018 and 7221.00.0030) or subheading 7222.11.00, 7222.19.00 or 7222.40.30 (except for statistical reporting numbers 7222.40.3025 and 7222.40.3045)	45,391 kg
9903.80.39	Blooms, billets and slabs of stainless steel and other products, provided for in subheading 7218.91.00 and 7218.99.00	110,360 kg
9903.80.40	Oil country pipe and tube goods of stainless steel and other products, provided for in subheading 7304.22.00, 7304.24.30, 7304.24.40, 7304.24.60, 7306.21.30, 7306.21.40 or 7306.21.80	3,500 kg
9903.80.41	Ingot and other primary forms of stainless steel, provided for in subheading 7218.10.00	215,467 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.42	Flat-rolled products of stainless steel, provided for in subheading 7219.21.00, 7219.22.00, 7219.31.00 (except for statistical reporting number 7219.31.0010) or 7220.11.00	2,329,416 kg
9903.80.43	Bars and rods, hot-rolled, in irregularly wound coils, of stainless steel, provided for in heading 7221.00.00 (except for statistical reporting numbers 7221.00.0005, 7221.00.0045 and 7221.00.0075)	0 kg
9903.80.44	Angles, shapes and sections of stainless steel, provided for in subheading 7222.40.30 (except for statistical reporting numbers 7222.40.3065 and 7222.40.3085) or 7222.40.60	49 kg
9903.80.45	Angles, shapes and sections, provided for in subheading 7216.31.00, 7216.32.00, 7216.33.00, 7216.40.00, 7216.50.00, 7216.99.00, 7228.70.30 (except for statistical reporting numbers 7228.70.3060 and 7228.70.3081) or 7228.70.60	106,760,293 kg
9903.80.46	Bars and rods, hot-rolled, in irregularly wound coils, provided for in subheading 7213.91.30, 9213.91.45, 7213.91.60, 7213.99.00 (except for statistical reporting number 7213.99.0060), 7227.20.00 (except for statistical reporting number 7227.20.0080) or 7227.90.60 (except for statistical reporting numbers 7227.90.6005, 7227.90.6010, 7227.90.6040 and 7227.90.6090)	56,474,925 kg
9903.80.47	Wire (other than of stainless steel), provided for in subheading 7217.10.10, 7217.10.20, 7217.10.30, 7217.10.40, 7217.10.50, 7217.10.60, 7217.10.70, 7217.10.80, 7217.10.90, 7217.20.15, 7217.20.30, 7217.20.45, 7217.20.60, 7217.20.75, 7217.30.15, 7217.30.30, 7217.30.45, 7217.30.60, 7217.30.75, 7217.90.10, 7217.90.50, 7229.20.00, 7229.90.10, 7229.90.50 or 7229.90.90	40,508,288 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.48	Bars, hot-rolled, not of stainless steel, provided for in subheading 7213.20.00, 7213.99.00 (except for statistical reporting numbers 7213.99.0030 and 7213.99.0090), 7214.10.00, 7214.30.00, 7214.91.00, 7214.99.00, 7215.90.10, 7227.20.00 (except for statistical reporting number 7227.20.0030), 7227.90.60 (except for statistical reporting numbers 7227.90.6020, 7227.90.6030 and 7227.90.6035), 7228.20.10, 7228.30.80 (except for statistical reporting number 7228.30.8010), 7228.40.00, 7228.60.60 or 7228.80.00	32,914,618 kg
9903.80.49	Bars, cold-finished, not of stainless steel, provided for in subheading 7215.10.00, 7215.50.00, 7215.90.30, 7215.90.50, 7228.20.50, 7228.50.50 or 7228.60.80	9,535,366 kg
9903.80.50	Angles, shapes and sections of a type known as "light-shaped bars" and other products, provided for in subheading 7216.10.00, 7216.21.00, 7216.22.00 or 7228.70.30 (except for statistical reporting numbers 7228.70.3010, 7228.70.3020 and 7228.70.3041)	1,150,356 kg
9903.80.51	Reinforcing bars, provided for in subheading 7213.10.00, 7214.20.00 or 7228.30.80 (except for statistical reporting numbers 7228.30.8005, 7228.30.8015, 7228.30.8041, 7228.30.8045 and 7228.30.8070)	4,400,770 kg
9903.80.52	Sheet piling, provided for in subheading 7301.10.00	0 kg
9903.80.53	Nonumerated railroad goods, provided for in subheading 7302.40.00, 7302.90.10 and 7302.90.90	109,715 kg
9903.80.54	Rails other than those known as "standard rails," provided for in subheading 7302.10.10 (except for statistical reporting numbers 7302.10.1010, 7302.10.1035, 7302.10.1065 and 7302.10.1075)	467 kg

Heading/ Subheading	Article description	Quantitative Limitation
9903.80.55	Rails known as "standard rails," provided for in subheading 7302.10.10 (except for statistical reporting numbers 7302.10.1015, 7302.10.1025, 7302.10.1045 and 7302.10.1055) or 7302.10.50	770 kg
9903.80.56	Products of tool steel and other products, provided for in subheading 7224.10.00 (except for statistical reporting numbers 7224.10.0005 and 7224.10.0075), 7224.90.00 (except for statistical reporting numbers 7224.90.0005, 7224.90.0045, 7224.90.0055, 7224.90.0065 and 7224.90.0075), 7225.30.11, 7225.30.51, 7225.40.11, 7225.40.51, 7225.50.11, 7226.20.00, 7226.91.05, 7226.91.15, 7226.91.25, 7226.92.10, 7226.92.30, 7227.10.00, 7227.90.10, 7227.90.20, 7228.10.00, 7228.30.20, 7228.30.40, 7228.30.60, 7228.50.10, 7228.60.10 or 7229.90.05	849,004 kg
9903.80.57	Blooms, billets and slabs, semi-finished, provided for in subheading 7207.11.00, 7207.12.00, 7207.19.00, 7207.20.00 or 7224.90.00 (except for statistical reporting numbers 7224.90.0015, 7224.90.0025, and 7224.90.0035)	1,697,955 kg
9903.80.58	Ingots, provided for in subheading 7206.10.00, 7206.90.00 or 7224.10.00 (except for statistical reporting number 7224.10.0045)	74,667 kg

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